

US3112389 (Prod: Medical Center For Clinical Research - M3 Wake Research)

Generated By: KC Joubran

Generated On: 09 Jun 2021 15:14:10

All time stamps listed in this document are displayed in GMT

US3112389

Form: Participant Creation

Data signed: (b) (4) 02 Apr 2021 22:02:24

Generated On: 09 Jun 2021 15:14:10

Participant ID

US3112389

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

US3112389

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 17:14:50

Generated On: 09 Jun 2021 15:14:10

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

Visit date (dd MMM yyyy)	26 AUG 2020
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	SCRN
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US3112389

Folder: Screening

Form: Demographics

Data signed: (b) (4) 19 Feb 2021 17:14:50

Generated On: 09 Jun 2021 15:14:10

Date of Birth (MMM yyyy)	(b) (6) 1951
Age	69
Age Units	YEARS
Age (Derived)	69
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input checked="" type="radio"/> Not Hispanic or Latino <input 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) 19 Feb 2021 17:14:50

Generated On: 09 Jun 2021 15:14:10

Date of Informed Consent (<i>dd MMM yyyy</i>)	26 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 type="radio"/>
	Amendment 3 <input checked="" 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) 19 Feb 2021 17:14:50

Generated On: 09 Jun 2021 15:14:10

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 19 Feb 2021 17:14:50

Generated On: 09 Jun 2021 15:14:10

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 09 Apr 2021 00:13:43

Generated On: 09 Jun 2021 15:14:10

Condition	HYPERCHOLESTEROLEMIA
Start date (dd MMM yyyy)	UN UNK 2020
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 2020
Start Year (derived)	2020
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 09 Apr 2021 00:13:43

Generated On: 09 Jun 2021 15:14:10

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

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 09 Apr 2021 00:13:43

Generated On: 09 Jun 2021 15:14:10

Condition	LEFT THIGH MASS
Start date (dd MMM yyyy)	UN JUN 2020
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)	JUN 2020
Start Year (derived)	2020
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 17:14:50

Generated On: 09 Jun 2021 15:14:10

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	26 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	14:05 (24 HR)
Vital Signs Date and Time (derived)	26 AUG 2020 14:05
Height (<i>xxx.x</i>)	63 in
Weight (<i>xxx.x</i>)	132 lb
BMI (<i>xxx.x</i>)	23.43164 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) 19 Feb 2021 17:14:50

Generated On: 09 Jun 2021 15:14:10

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

26 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) 19 Feb 2021 17:14:50

Generated On: 09 Jun 2021 15:14:10

Date of assessment (dd MMM yyyy) 26 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 True

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 17:14:50

Generated On: 09 Jun 2021 15:14:10

Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☒ No ☐

Specify

(b) (6) FINANCIAL
PROFESSIONAL (FREQUENT
AIRLINE TRAVELER)

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 17:14:50

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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	False
Specify	

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 22:01:20

Generated On: 09 Jun 2021 15:14:10

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	26 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) 12 Feb 2021 22:01:20

Generated On: 09 Jun 2021 15:14:10

What was the date of randomization? (dd MMM yyyy) 26 AUG 2020

What was the participant's randomization number? 188573

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) 12 Feb 2021 22:01:20

Generated On: 09 Jun 2021 15:14:10

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) 12 Feb 2021 22:01:20

Generated On: 09 Jun 2021 15:14:10

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)	26 AUG 2020
Time of assessment (00:00-23:59)	14:05 (24 HR)
Vital Signs Date and Time (derived)	26 AUG 2020 14:05
Temperature (xxx.x)	98.5 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	71 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	85 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 22:01:20

Generated On: 09 Jun 2021 15:14:10

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)	26 AUG 2020
Time of assessment (00:00-23:59)	16:05 (24 HR)
Vital Signs Date and Time (derived)	26 AUG 2020 16:05
Temperature (xxx.x)	97.2 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	116 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 22:01:20

Generated On: 09 Jun 2021 15:14:10

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 22:01:20

Generated On: 09 Jun 2021 15:14:10

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) 26 AUG 2020

What was the treatment time? (00:00-23:59) 15:34 (24 HR)

Treatment Date and Time (derived) 26 AUG 2020 15:34

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) 12 Feb 2021 22:01:20

Generated On: 09 Jun 2021 15:14:10

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	26 AUG 2020
Collection time (00:00-23:59)	15:09 (24 HR)
Collection date and time (derived)	26 AUG 2020 15:09

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Feb 2021 22:01:20

Generated On: 09 Jun 2021 15:14:10

Collection date (dd MMM yyyy)			26 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:48	26 AUG 2020 14:48
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 22:01:20

Generated On: 09 Jun 2021 15:14:10

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 15:14:10

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

26 AUG 2020 16:06

PC Open Date & Time

26 AUG 2020 15:54

PC Close Date & Time

26 AUG 2020 18:24

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.5 °F

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

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

PC Time Stamp	27 AUG 2020 00:31
PC Open Date & Time	26 AUG 2020 19:19
PC Close Date & Time	27 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.1 °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

27 AUG 2020 17:45

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3112389

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:14:10

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

96.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

29 AUG 2020 00:06

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3112389

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:14:10

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

95.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

30 AUG 2020 00:57

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:14:10

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

96.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

30 AUG 2020 22:13

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3112389

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:14:10

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

95.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

31 AUG 2020 23:53

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3112389

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.0 °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

01 SEP 2020 21:02

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3112389

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

26 AUG 2020 16:07

PC Open Date & Time

26 AUG 2020 15:54

PC Close Date & Time

26 AUG 2020 18:24

US3112389

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:14:10

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

27 AUG 2020 00:33

PC Open Date & Time

26 AUG 2020 19:19

PC Close Date & Time

27 AUG 2020 11:59

US3112389

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:14:10

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

27 AUG 2020 17:46

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3112389

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:14:10

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

29 AUG 2020 00:07

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3112389

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:14:10

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

30 AUG 2020 00:58

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3112389

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:14:10

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

30 AUG 2020 22:14

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3112389

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:14:10

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

31 AUG 2020 23:53

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3112389

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:14:10

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

01 SEP 2020 21:03

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3112389

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:14:10

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 ☐

US3112389

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:14:10

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

No ☒

Yes ☐

PC Time stamp	26 AUG 2020 16:08
PC Open Date & Time	26 AUG 2020 15:54
PC Close Date & Time	26 AUG 2020 18:24

US3112389

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:14:10

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 ☐

US3112389

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:14:10

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

No ☒

Yes ☐

PC Time stamp	27 AUG 2020 00:34
PC Open Date & Time	26 AUG 2020 19:19
PC Close Date & Time	27 AUG 2020 11:59

US3112389

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3112389

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:14:10

Yes <input type="checkbox"/>	
PC Time stamp	27 AUG 2020 17:48
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

US3112389

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

DAY 3

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:14:10

Yes <input type="checkbox"/>	
PC Time stamp	29 AUG 2020 00:09
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59

US3112389

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:14:10

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

49 of 2259

EAB) (1725)

US3112389

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:14:10

Yes <input type="checkbox"/>	
PC Time stamp	30 AUG 2020 01:00
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3112389

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:14:10

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

51 of 2259

EAB) (1725)

US3112389

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:14:10

Yes <input type="checkbox"/>	
PC Time stamp	30 AUG 2020 22:16
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3112389

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

53 of 2259

EAB) (1725)

US3112389

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:14:10

Yes <input type="checkbox"/>	
PC Time stamp	31 AUG 2020 23:54
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

US3112389

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:14:10

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

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EAB) (1725)

US3112389

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:14:10

Yes <input type="checkbox"/>	
PC Time stamp	01 SEP 2020 21:04
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3112389

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 22:01:20

Generated On: 09 Jun 2021 15:14:10

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

2 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3112389

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 22:01:20

Generated On: 09 Jun 2021 15:14:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112389

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 22:01:20

Generated On: 09 Jun 2021 15:14:10

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

US3112389

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 22:01:20

Generated On: 09 Jun 2021 15:14:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112389

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 22:01:20

Generated On: 09 Jun 2021 15:14:10

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 16 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3112389

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 22:01:20

Generated On: 09 Jun 2021 15:14:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112389

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 22:01:20

Generated On: 09 Jun 2021 15:14:10

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	23 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

US3112389

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Feb 2021 22:01:20

Generated On: 09 Jun 2021 15:14:10

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	23 SEP 2020
Time of assessment (00:00-23:59)	14:39 (24 HR)
Vital Signs Date and Time (derived)	23 SEP 2020 14:39
Temperature (xxx.x)	98.8 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	119 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	078 mmHg
Diastolic Blood Pressure units	MMHG

US3112389

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 22:01:20

Generated On: 09 Jun 2021 15:14:10

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)	23 SEP 2020
Time of assessment (00:00-23:59)	15:59 (24 HR)
Vital Signs Date and Time (derived)	23 SEP 2020 15:59
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	66 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	100 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	068 mmHg
Diastolic Blood Pressure units	MMHG

US3112389

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 22:01:20

Generated On: 09 Jun 2021 15:14:10

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

23 SEP 2020

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

US3112389

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 22:01:20

Generated On: 09 Jun 2021 15:14:10

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) 23 SEP 2020

What was the treatment time? (00:00-23:59) 15:25 (24 HR)

Treatment Date and Time (derived) 23 SEP 2020 15:25

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

US3112389

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 22:01:20

Generated On: 09 Jun 2021 15:14:10

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

23 SEP 2020

Collection time (00:00-23:59)

15:04 (24 HR)

Collection date and time (derived)

23 SEP 2020 15:04

US3112389

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Feb 2021 22:01:20

Generated On: 09 Jun 2021 15:14:10

Collection date (dd MMM yyyy)			23 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:56	23 SEP 2020 14:56
Nasopharyngeal Swab 2	No		

US3112389

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 22:01:20

Generated On: 09 Jun 2021 15:14:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112389

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:14:10

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

97.9 °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

23 SEP 2020 15:56

PC Open Date & Time

23 SEP 2020 15:45

PC Close Date & Time

23 SEP 2020 18:15

US3112389

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.8 °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	23 SEP 2020 22:10
PC Open Date & Time	23 SEP 2020 19:10
PC Close Date & Time	24 SEP 2020 11:59

US3112389

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °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 SEP 2020 09:26

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3112389

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:14:10

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

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

25 SEP 2020 12:35

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3112389

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °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

26 SEP 2020 12:50

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3112389

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

27 SEP 2020 22:39

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3112389

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °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

29 SEP 2020 09:07

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3112389

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.1 °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

30 SEP 2020 06:53

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3112389

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

23 SEP 2020 15:56

PC Open Date & Time

23 SEP 2020 15:45

PC Close Date & Time

23 SEP 2020 18:15

US3112389

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:14:10

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

23 SEP 2020 22:10

PC Open Date & Time

23 SEP 2020 19:10

PC Close Date & Time

24 SEP 2020 11:59

US3112389

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:14:10

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

25 SEP 2020 09:25

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3112389

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:14:10

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

10

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

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 SEP 2020 12:38

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3112389

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:14:10

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 ☐

Please record - **REDNESS AT INJECTION SITE (in mm)**

9

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

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

Yes ☒

No ☐

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

1

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

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

26 SEP 2020 12:53

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3112389

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:14:10

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 ☐

Please record - **REDNESS AT INJECTION SITE (in mm)**

9

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

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

Yes ☐

No ☒

Please record - **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

27 SEP 2020 22:42

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3112389

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:14:10

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

29 SEP 2020 09:08

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3112389

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:14:10

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

30 SEP 2020 06:53

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3112389

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:14:10

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 ☐

US3112389

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:14:10

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

No ☒

Yes ☐

PC Time stamp	23 SEP 2020 15:57
PC Open Date & Time	23 SEP 2020 15:45
PC Close Date & Time	23 SEP 2020 18:15

US3112389

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:14:10

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 ☐

US3112389

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:14:10

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

No ☒

Yes ☐

PC Time stamp	23 SEP 2020 22:11
PC Open Date & Time	23 SEP 2020 19:10
PC Close Date & Time	24 SEP 2020 11:59

US3112389

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:14:10

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)

US3112389

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:14:10

Yes <input type="checkbox"/>	
PC Time stamp	25 SEP 2020 09:29
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

US3112389

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:14:10

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 ☒

US3112389

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:14:10

Yes <input type="checkbox"/>	
PC Time stamp	25 SEP 2020 12:39
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

US3112389

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:14:10

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 ☒

US3112389

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:14:10

Yes <input type="checkbox"/>	
PC Time stamp	26 SEP 2020 12:54
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

US3112389

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:14:10

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 ☒

US3112389

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:14:10

Yes <input type="checkbox"/>	
PC Time stamp	28 SEP 2020 06:34
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

US3112389

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:14:10

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 ☒

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EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:14:10

Yes <input type="checkbox"/>	
PC Time stamp	29 SEP 2020 09:09
PC Open Date & Time	28 SEP 2020 12:00
PC Close Date & Time	29 SEP 2020 11:59

US3112389

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:14:10

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 ☒

US3112389

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:14:10

Yes <input type="checkbox"/>	
PC Time stamp	30 SEP 2020 06:54
PC Open Date & Time	29 SEP 2020 12:00
PC Close Date & Time	30 SEP 2020 11:59

US3112389

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

None ☒

FATIGUE

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

30 SEP 2020 14:32

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3112389

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	30 SEP 2020 14:32
PC Open Date & Time	30 SEP 2020 12:00
PC Close Date & Time	01 OCT 2020 11:59

US3112389

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 22:01:20

Generated On: 09 Jun 2021 15:14:10

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

US3112389

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 22:01:20

Generated On: 09 Jun 2021 15:14:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112389

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 22:01:20

Generated On: 09 Jun 2021 15:14:10

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

7 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3112389

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 22:01:20

Generated On: 09 Jun 2021 15:14:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112389

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 22:01:20

Generated On: 09 Jun 2021 15:14:10

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3112389

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 22:01:20

Generated On: 09 Jun 2021 15:14:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112389

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 22:01:20

Generated On: 09 Jun 2021 15:14:10

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	22 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

US3112389

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Feb 2021 22:01:20

Generated On: 09 Jun 2021 15:14:10

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	22 OCT 2020
Time of assessment (00:00-23:59)	14:21 (24 HR)
Vital Signs Date and Time (derived)	22 OCT 2020 14:21
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	79 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	111 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	77 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3112389

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 22:01:20

Generated On: 09 Jun 2021 15:14:10

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.

US3112389

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 22:01:20

Generated On: 09 Jun 2021 15:14:10

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	22 OCT 2020
Collection time (00:00-23:59)	14:30 (24 HR)
Collection date and time (derived)	22 OCT 2020 14:30

US3112389

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 22:01:20

Generated On: 09 Jun 2021 15:14:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112389

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

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

26 OCT 2020 07:05:09

Patient Cloud Open Date & Time

26 OCT 2020 00:01

Patient Cloud Close Date & Time

30 OCT 2020 23:59

US3112389

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 NOV 2020 16:42:00

Patient Cloud Open Date & Time

02 NOV 2020 00:01

Patient Cloud Close Date & Time

06 NOV 2020 23:59

US3112389

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	10 NOV 2020 05:28:42
Patient Cloud Open Date & Time	09 NOV 2020 00:01
Patient Cloud Close Date & Time	13 NOV 2020 23:59

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	23 NOV 2020 10:18:22
Patient Cloud Open Date & Time	20 NOV 2020 00:01
Patient Cloud Close Date & Time	24 NOV 2020 23:59

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

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	30 NOV 2020 08:01:03
Patient Cloud Open Date & Time	27 NOV 2020 00:01
Patient Cloud Close Date & Time	01 DEC 2020 23:59

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

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

04 DEC 2020 08:47:17

Patient Cloud Open Date & Time

04 DEC 2020 00:01

Patient Cloud Close Date & Time

08 DEC 2020 23:59

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	11 DEC 2020 00:01
Patient Cloud Close Date & Time	15 DEC 2020 23:59

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

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

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

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 ☐
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 ☐

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

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

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

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="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"/>

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

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

[Patient Cloud Close Date & Time](#)

05 JAN 2021 23:59

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

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

08 JAN 2021 09:35:32

Patient Cloud Open Date & Time

08 JAN 2021 00:01

Patient Cloud Close Date & Time

12 JAN 2021 23:59

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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	19 JAN 2021 12:18:46
Patient Cloud Open Date & Time	15 JAN 2021 00:01
Patient Cloud Close Date & Time	19 JAN 2021 23:59

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 JAN 2021 09:32:51

Patient Cloud Open Date & Time

22 JAN 2021 00:01

Patient Cloud Close Date & Time

26 JAN 2021 23:59

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT	DAY 159
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	31 JAN 2021 06:58:47
Patient Cloud Open Date & Time	29 JAN 2021 00:01
Patient Cloud Close Date & Time	02 FEB 2021 23:59

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	09 FEB 2021 04:37:07
Patient Cloud Open Date & Time	05 FEB 2021 00:01
Patient Cloud Close Date & Time	09 FEB 2021 23:59

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

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

14 FEB 2021 12:15:15

Patient Cloud Open Date & Time

12 FEB 2021 00:01

Patient Cloud Close Date & Time

16 FEB 2021 23:59

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

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

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

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

26 FEB 2021 16:58:21

Patient Cloud Open Date & Time

26 FEB 2021 00:01

Patient Cloud Close Date & Time

02 MAR 2021 23:59

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

DAY 194

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

07 MAR 2021 12:12:13

Patient Cloud Open Date & Time

05 MAR 2021 00:01

Patient Cloud Close Date & Time

09 MAR 2021 23:59

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

13 MAR 2021 10:56:58

Patient Cloud Open Date & Time

12 MAR 2021 00:01

Patient Cloud Close Date & Time

16 MAR 2021 23:59

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

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

23 MAR 2021 08:59:25

Patient Cloud Open Date & Time

19 MAR 2021 00:01

Patient Cloud Close Date & Time

23 MAR 2021 23:59

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

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

29 MAR 2021 10:58:59

Patient Cloud Open Date & Time

26 MAR 2021 00:01

Patient Cloud Close Date & Time

30 MAR 2021 23:59

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

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

02 APR 2021 00:14:38

Patient Cloud Open Date & Time

02 APR 2021 00:01

Patient Cloud Close Date & Time

06 APR 2021 23:59

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

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

13 APR 2021 09:29:48

Patient Cloud Open Date & Time

09 APR 2021 00:01

Patient Cloud Close Date & Time

13 APR 2021 23:59

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

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

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

20 APR 2021 23:59

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

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

24 APR 2021 08:48:00

Patient Cloud Open Date & Time

23 APR 2021 00:01

Patient Cloud Close Date & Time

27 APR 2021 23:59

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°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"/>

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

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

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

DAY 257

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

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

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

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

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

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

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

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

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

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

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

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"/>

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2021 23:59

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

DAY 271

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

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

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

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

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

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

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

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

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

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 ☐

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

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

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT	DAY 285
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°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"/>

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

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

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

DAY 292

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

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

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

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

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

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

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

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

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

15 JUN 2021 23:59

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

DAY 299

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

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

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

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

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

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

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 ☐

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

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

[Patient Cloud Open Date & Time](#)

18 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

22 JUN 2021 23:59

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

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

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 ☐

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

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

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

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 ☐

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

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

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

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

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JUL 2021 23:59

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

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="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"/>

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

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

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

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"/>

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

27 JUL 2021 23:59

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

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

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

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

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

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

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

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

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

DAY 355

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

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

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

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

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

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

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

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

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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
Patient Cloud Close Date & Time	17 AUG 2021 23:59

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

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"/>

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

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

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

DAY 369

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

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

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

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 ☐

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

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

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

DAY 383

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

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

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

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

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

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

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

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

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

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

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

DAY 390

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

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

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

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

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

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

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

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

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

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

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

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 ☐

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

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

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

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"/>

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

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

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

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"/>

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

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

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

DAY 418

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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
Patient Cloud Close Date & Time	19 OCT 2021 23:59

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

DAY 425

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

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

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

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

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

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

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

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

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

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

Patient Cloud Open Date & Time	22 OCT 2021 00:01
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Patient Cloud Close Date & Time	26 OCT 2021 23:59
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US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

DAY 432

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

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

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

DAY 439

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

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

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

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°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="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"/>

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

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

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

DAY 453

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

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

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

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"/>

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

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

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

DAY 467

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

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

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

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

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

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

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

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

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

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

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

DAY 474

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

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

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

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

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

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

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

DAY 488

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

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

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

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

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

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

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

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

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

DAY 495

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

04 JAN 2022 23:59

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

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 ☐

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

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

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

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 ☐

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

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

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

DAY 516

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

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

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

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°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 ☐

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

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

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

DAY 530

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

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

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

DAY 537

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

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

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

DAY 544

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

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

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

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

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

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

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

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

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

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 ☐

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

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

[Patient Cloud Close Date & Time](#)

01 MAR 2022 23:59

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

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 ☐

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

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

[Patient Cloud Close Date & Time](#)

08 MAR 2022 23:59

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

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 ☐

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

15 MAR 2022 23:59

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

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 ☐

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

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

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

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 ☐

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

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

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

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 ☐

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

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

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

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°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 ☐

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

12 APR 2022 23:59

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

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

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

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

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

DAY 607

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

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

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

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"/>

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

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

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

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="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"/>

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

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

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

DAY 628

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

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

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

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

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

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

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

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

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

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

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

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

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

DAY 642

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

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

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

DAY 649

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

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

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

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

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

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

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 ☐

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

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

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

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

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

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

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

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 ☐

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

21 JUN 2022 23:59

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

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="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"/>

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

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

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

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 ☐

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

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

[Patient Cloud Open Date & Time](#)

01 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JUL 2022 23:59

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

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"/>

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

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

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

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"/>

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

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

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

DAY 698

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

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

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

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"/>

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

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

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

DAY 712

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

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

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

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"/>

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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
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Patient Cloud Close Date & Time	16 AUG 2022 23:59
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US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

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"/>

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

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

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

DAY 733

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

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

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

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

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

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

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

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

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

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

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

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

[Patient Cloud Open Date & Time](#)

02 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

06 SEP 2022 23:59

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

DAY 747

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

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

[Patient Cloud Open Date & Time](#)

09 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

13 SEP 2022 23:59

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

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 ☐

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

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

[Patient Cloud Open Date & Time](#)

16 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

20 SEP 2022 23:59

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

DAY 761

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

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

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

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 ☐

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

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

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

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 ☐

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

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

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

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 ☐

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

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

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

DAY 789

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

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

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

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

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

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

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

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

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

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

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

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"/>

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

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

28 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

01 NOV 2022 23:59

US3112389

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 15:14:10

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
Yes	No	07 MAR 2021 12:12:54

US3112389

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 20:00:57

Generated On: 09 Jun 2021 15:14:10

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 19 NOV 2020

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

Comments

If Contact Not Made, please provide Comments

US3112389

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 20:00:57

Generated On: 09 Jun 2021 15:14:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112389

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 22:02:25

Generated On: 09 Jun 2021 15:14:10

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3112389

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 22:02:25

Generated On: 09 Jun 2021 15:14:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112389

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 22:02:35

Generated On: 09 Jun 2021 15:14:10

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

SUBJECT IN CONVALESCENT
PHASE

If Contact Not Made, please provide Comments

US3112389

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 22:02:25

Generated On: 09 Jun 2021 15:14:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112389

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 22:02:36

Generated On: 09 Jun 2021 15:14:10

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 22 FEB 2021

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

Comments

If Contact Not Made, please provide Comments

US3112389

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 22:02:35

Generated On: 09 Jun 2021 15:14:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112389

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 23 Apr 2021 21:06:22

Generated On: 09 Jun 2021 15:14:10

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

Visit date (dd MMM yyyy)	25 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
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US3112389

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 23 Apr 2021 21:06:22

Generated On: 09 Jun 2021 15:14:10

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	25 MAR 2021
Time of assessment (00:00-23:59)	14:31 (24 HR)
Vital Signs Date and Time (derived)	25 MAR 2021 14:31
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	73 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	111 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	73 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3112389

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Apr 2021 21:06:22

Generated On: 09 Jun 2021 15:14:10

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

25 MAR 2021

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

US3112389

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Apr 2021 21:06:21

Generated On: 09 Jun 2021 15:14:10

Was the sample collected? Yes ☒
No ☐

Collection date (dd MMM yyyy) 25 MAR 2021

Collection time (00:00-23:59) 15:12 (24 HR)

Collection date and time (derived) 25 MAR 2021 15:12

US3112389

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 23 Apr 2021 21:06:21

Generated On: 09 Jun 2021 15:14:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112389

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 23 Apr 2021 21:06:21

Generated On: 09 Jun 2021 15:14:10

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 21 APR 2021

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

Comments

If Contact Not Made, please provide Comments

US3112389

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 23 Apr 2021 21:06:21

Generated On: 09 Jun 2021 15:14:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112389

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:14:10

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

US3112389

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:14:10

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3112389

Folder: Covid-19 Assessment 20 Jan 2021

Form: COVID-19 Contact

Data signed: (b) (4) 02 Apr 2021 22:02:24

Generated On: 09 Jun 2021 15:14:10

Date of Contact	20 JAN 2021
Time of Contact	16:12
Date and Time of Contact (derived)	20 JAN 2021 16:12
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>

US3112389

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (1)

Data signed: (b) (4) 02 Apr 2021 22:02:24

Generated On: 09 Jun 2021 15:14:10

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"/>

US3112389

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (1)

Data signed: (b) (4) 02 Apr 2021 22:02:24

Generated On: 09 Jun 2021 15:14:10

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

Date	15 JAN 2021
------	-------------

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

O2 Saturation	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 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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US3112389

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (1)

Data signed: (b) (4) 02 Apr 2021 22:02:24

Generated On: 09 Jun 2021 15:14:10

	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"/>

US3112389

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (1)

Data signed: (b) (4) 02 Apr 2021 22:02:24

Generated On: 09 Jun 2021 15:14:10

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"/>

US3112389

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (2)

Data signed: (b) (4) 02 Apr 2021 22:02:24

Generated On: 09 Jun 2021 15:14:10

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"/>

US3112389

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (2)

Data signed: (b) (4) 02 Apr 2021 22:02:24

Generated On: 09 Jun 2021 15:14:10

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

Date	16 JAN 2021
------	-------------

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

O2 Saturation	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 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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Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (2)

Data signed: (b) (4) 02 Apr 2021 22:02:24

Generated On: 09 Jun 2021 15:14:10

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

US3112389

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (2)

Data signed: (b) (4) 02 Apr 2021 22:02:24

Generated On: 09 Jun 2021 15:14:10

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"/>

US3112389

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (3)

Data signed: (b) (4) 02 Apr 2021 22:02:24

Generated On: 09 Jun 2021 15:14:10

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"/>

US3112389

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (3)

Data signed: (b) (4) 02 Apr 2021 22:02:24

Generated On: 09 Jun 2021 15:14:10

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

Date	17 JAN 2021
------	-------------

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

O2 Saturation	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 checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

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

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

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Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (3)

Data signed: (b) (4) 02 Apr 2021 22:02:24

Generated On: 09 Jun 2021 15:14:10

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

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Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (3)

Data signed: (b) (4) 02 Apr 2021 22:02:24

Generated On: 09 Jun 2021 15:14:10

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 20 Jan 2021

Form: Symptom Log (4)

Data signed: (b) (4) 02 Apr 2021 22:02:24

Generated On: 09 Jun 2021 15:14:10

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 20 Jan 2021

Form: Symptom Log (4)

Data signed: (b) (4) 02 Apr 2021 22:02:24

Generated On: 09 Jun 2021 15:14:10

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

Date	18 JAN 2021
------	-------------

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

O2 Saturation	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 checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

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

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

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Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (4)

Data signed: (b) (4) 02 Apr 2021 22:02:24

Generated On: 09 Jun 2021 15:14:10

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

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Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (4)

Data signed: (b) (4) 02 Apr 2021 22:02:24

Generated On: 09 Jun 2021 15:14:10

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 20 Jan 2021

Form: Symptom Log (5)

Data signed: (b) (4) 02 Apr 2021 22:02:24

Generated On: 09 Jun 2021 15:14:10

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 20 Jan 2021

Form: Symptom Log (5)

Data signed: (b) (4) 02 Apr 2021 22:02:24

Generated On: 09 Jun 2021 15:14:10

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

Date	19 JAN 2021
------	-------------

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

O2 Saturation	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 checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

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

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

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Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (5)

Data signed: (b) (4) 02 Apr 2021 22:02:24

Generated On: 09 Jun 2021 15:14:10

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

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Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (5)

Data signed: (b) (4) 02 Apr 2021 22:02:24

Generated On: 09 Jun 2021 15:14:10

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 20 Jan 2021

Form: Symptom Log (6)

Data signed: (b) (4) 02 Apr 2021 22:02:24

Generated On: 09 Jun 2021 15:14:10

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) 02 Apr 2021 22:02:24

Generated On: 09 Jun 2021 15:14:10

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

Date	20 JAN 2021
------	-------------

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

O2 Saturation	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 checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

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

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

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Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (6)

Data signed: (b) (4) 02 Apr 2021 22:02:24

Generated On: 09 Jun 2021 15:14:10

	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 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"/>

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Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (6)

Data signed: (b) (4) 02 Apr 2021 22:02:24

Generated On: 09 Jun 2021 15:14:10

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 20 Jan 2021

Form: Symptom Log (7)

Data signed: (b) (4) 02 Apr 2021 22:02:24

Generated On: 09 Jun 2021 15:14:10

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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Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (7)

Data signed: (b) (4) 02 Apr 2021 22:02:24

Generated On: 09 Jun 2021 15:14:10

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

Date	21 JAN 2021
------	-------------

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

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

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

Temperature	97.7 F
-------------	--------

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

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

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

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

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EAB) (1725)

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Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (7)

Data signed: (b) (4) 02 Apr 2021 22:02:24

Generated On: 09 Jun 2021 15:14:10

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

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Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (7)

Data signed: (b) (4) 02 Apr 2021 22:02:24

Generated On: 09 Jun 2021 15:14:10

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 20 Jan 2021

Form: COVID Diagnostic Test

Data signed: (b) (4) 02 Apr 2021 22:02:24

Generated On: 09 Jun 2021 15:14:10

Date of Visit 21 JAN 2021

Was the Subject Tested For SARS-CoV-2 by RT-PCR? Yes ☒
No ☐

Did Subject Test Positive For SARS-CoV-2 by RT-PCR? Yes ☐
No ☒

Date of Test 21 JAN 2021

Type of Test Performed Nasopharyngeal Swab ☒
Nasal Swab ☐
Saliva Test ☐
Other ☐

Other, specify

Was this diagnostic test performed at a lab other than the Study Central Lab? Yes ☒
No ☐

If yes, provide lab information below

Lab/ Institution Test Performed COUNTY OF SAN DIEGO
TESTING SITE

CLIA Certified? Yes ☒
No ☐

COVID-19 Positive (CSA Programming Field Only) 0

US3112389

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 02 Apr 2021 22:02:24

Generated On: 09 Jun 2021 15:14:10

Visit	Was Saliva Collected?	Date of Collection
Day 3	NA (COVID-19 Negative)	
Day 5	NA (COVID-19 Negative)	
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)	

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Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 22:02:25

Generated On: 09 Jun 2021 15:14:10

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

Visit date (dd MMM yyyy)	21 JAN 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	SICKD1
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US3112389

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 02 Apr 2021 22:02:25

Generated On: 09 Jun 2021 15:14:10

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	21 JAN 2021
Time of assessment (<i>00:00-23:59</i>)	14:17 (24 HR)
Vital Signs Date and Time (derived)	21 JAN 2021 14:17
Height (<i>xxx.x</i>)	ND - Not Done
Weight (<i>xxx.x</i>)	ND - Not Done
Temperature (<i>xxx.x</i>)	97.7 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	76 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	112 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	76 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3112389

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 22:02:25

Generated On: 09 Jun 2021 15:14:10

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

21 JAN 2021

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

US3112389

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 02 Apr 2021 22:02:25

Generated On: 09 Jun 2021 15:14:10

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

21 JAN 2021

US3112389

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

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 22:02:25

Generated On: 09 Jun 2021 15:14:10

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

Visit date (dd MMM yyyy)	7 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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US3112389

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

Form: Unblinding

Data signed: (b) (4) 09 Apr 2021 00:13:43

Generated On: 09 Jun 2021 15:14:10

Date of updated informed consent (dd MMM yyyy) 7 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) 7 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 _____

US3112389

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 02 Apr 2021 22:02:25

Generated On: 09 Jun 2021 15:14:10

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

Collection date (dd MMM yyyy)	7 JAN 2021
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Collection time (00:00-23:59)	11:47 (24 HR)
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Collection date and time (derived)	7 JAN 2021 11:47
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US3112389

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 02 Apr 2021 22:02:25

Generated On: 09 Jun 2021 15:14:10

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	7 JAN 2021
Collection time (00:00 - 23:59)	11:35
Collection Date and Time (derived)	7 JAN 2021 11:35

US3112389

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 19 Mar 2021 20:34:25

Generated On: 09 Jun 2021 15:14:10

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3112389

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 09 Apr 2021 00:13:43

Generated On: 09 Jun 2021 15:14:10

AEID	
Adverse event	UTI
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)	10 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	15 NOV 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 09 Apr 2021 00:13:43

Generated On: 09 Jun 2021 15:14:10

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

US3112389

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 09 Apr 2021 00:13:43

Generated On: 09 Jun 2021 15:14:10

AEID	
Adverse event	VIRAL SYNDROME
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)	15 JAN 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	24 JAN 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 09 Apr 2021 00:13:43

Generated On: 09 Jun 2021 15:14:10

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

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 09 Apr 2021 00:13:43

Generated On: 09 Jun 2021 15:14:10

AEID	USA-US062-2021-MRNA-1273-P30 1000013
Adverse event	LEFT THIGH LIPOSARCOMA
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)	02 DEC 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	09 MAR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	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) 09 Apr 2021 00:13:43

Generated On: 09 Jun 2021 15:14:10

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 Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	False
Concomitant Procedure	True
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	PT. DX AND TREATED FOR LEFT THIGH LIPOSARCOMA. EXCISED 09MAR2021. NO FURTHER TREATMENT PLANNED AT THIS TIME. FOLLOW UP IN 6 MONTHS PER THEIR SPECIALIST.

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 09 Apr 2021 00:13:43

Generated On: 09 Jun 2021 15:14:10

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)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 02 Apr 2021 22:02:24

Generated On: 09 Jun 2021 15:14:10

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

Yes ☒

No ☐

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

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 02 Apr 2021 22:02:24

Generated On: 09 Jun 2021 15:14:10

Name of Medication PRAVASTATIN

Prophylaxis Yes ☐
No ☒

Indication HYPERCHOLESTEROLEMIA

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 02 Apr 2021 22:02:24

Generated On: 09 Jun 2021 15:14:10

	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 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 02 Apr 2021 22:02:24

Generated On: 09 Jun 2021 15:14:10

Name of Medication ESTRADIOL

Prophylaxis Yes ☐
No ☒

Indication POST MENOPAUSAL HOT
FLASHES

Dose per administration 2

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 02 Apr 2021 22:02:24

Generated On: 09 Jun 2021 15:14:10

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 02 Apr 2021 22:02:24

Generated On: 09 Jun 2021 15:14:10

Name of Medication MULTIVITAMIN

Prophylaxis Yes ☒
No ☐

Indication SUPPLEMENT

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 02 Apr 2021 22:02:24

Generated On: 09 Jun 2021 15:14:10

	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 2000
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 02 Apr 2021 22:02:24

Generated On: 09 Jun 2021 15:14:10

Name of Medication VITAMIN D

Prophylaxis Yes ☐
No ☒

Indication SUPPLEMENT

Dose per administration 2000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 02 Apr 2021 22:02:24

Generated On: 09 Jun 2021 15:14:10

	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"/>

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 02 Apr 2021 22:02:24

Generated On: 09 Jun 2021 15:14:10

Name of Medication VITAMIN E

Prophylaxis Yes ☐
No ☒

Indication SUPPLEMENT

Dose per administration 400

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 02 Apr 2021 22:02:24

Generated On: 09 Jun 2021 15:14:10

	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 2015	
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)	2	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 02 Apr 2021 22:02:24

Generated On: 09 Jun 2021 15:14:10

Name of Medication GLUCOSAMINE

Prophylaxis Yes ☐
No ☒

Indication SUPPLEMENT

Dose per administration 2

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 02 Apr 2021 22:02:24

Generated On: 09 Jun 2021 15:14:10

	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 2015	
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"/>

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 02 Apr 2021 22:02:24

Generated On: 09 Jun 2021 15:14:10

Name of Medication VITAMIN C

Prophylaxis Yes ☐
No ☒

Indication SUPPLEMENT

Dose per administration 2015

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 02 Apr 2021 22:02:24

Generated On: 09 Jun 2021 15:14:10

	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 2015	
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"/>

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 02 Apr 2021 22:02:24

Generated On: 09 Jun 2021 15:14:10

Name of Medication FLU VACCINE

Prophylaxis Yes ☒
No ☐

Indication FLU PROPHYLAXIS

Dose per administration .5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 02 Apr 2021 22:02:24

Generated On: 09 Jun 2021 15:14:10

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 02 Apr 2021 22:02:24

Generated On: 09 Jun 2021 15:14:10

Name of Medication MACROBID

Prophylaxis Yes ☐
No ☒

Indication UTI

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 (9)

Data signed: (b) (4) 02 Apr 2021 22:02:24

Generated On: 09 Jun 2021 15:14:10

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	10 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	15 NOV 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
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 (10)

Data signed: (b) (4) 02 Apr 2021 22:02:24

Generated On: 09 Jun 2021 15:14:10

Name of Medication PNEUMOCOCCAL VACCINE

Prophylaxis Yes ☒
No ☐

Indication PNEUMONIA PREVENTION
PROPHYLAXIS

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 02 Apr 2021 22:02:24

Generated On: 09 Jun 2021 15:14:10

	Intraocular	<input type="radio"/>
	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	02 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		02 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 02 Apr 2021 22:02:24

Generated On: 09 Jun 2021 15:14:10

Name of Medication BOTOX

Prophylaxis Yes ☐
No ☒

Indication COSMETIC

Dose per administration UNKNOWN

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

If dose unit is Other, specify UNKNOWN

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 (11)

Data signed: (b) (4) 02 Apr 2021 22:02:24

Generated On: 09 Jun 2021 15:14:10

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2017
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) UN UNK 2017		
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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 02 Apr 2021 22:02:24

Generated On: 09 Jun 2021 15:14:10

Name of Medication JUVEDERM

Prophylaxis Yes ☐
No ☒

Indication COSMETIC

Dose per administration UNKNOWN

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

If dose unit is Other, specify UNKNOWN

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 (12)

Data signed: (b) (4) 02 Apr 2021 22:02:24

Generated On: 09 Jun 2021 15:14:10

	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 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) UN UNK 2015		
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"/>

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 09 Apr 2021 00:13:43

Generated On: 09 Jun 2021 15:14:10

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 09 Apr 2021 00:13:43

Generated On: 09 Jun 2021 15:14:10

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
09 MAR 2021	LIPOSARCOMA EXCISION	Adverse Event	

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 15:14:10

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

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 15:14:10

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 ☐

US3112389

Folder: SAE USA-US062-2021-MRNA-1273-P301000013

Form: Safety Report Form

Data signed: (b) (4) 15 Apr 2021 23:40:44

Generated On: 09 Jun 2021 15:14:10

SAEID	USA-US062-2021-MRNA-1273-P301000013
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	TODD
Investigator's Last Name	SIMMONS
Site Address: Street	9040 FRIARS ROAD SUITE 540
Site Address: City	SAN DIEGO
Site Address: State	CA
Site Address: Postal Code	92108
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4

US3112389

Folder: SAE USA-US062-2021-MRNA-1273-P301000013

Form: Safety Report Form (1)

Data signed: (b) (4) 15 Apr 2021 23:40:44

Generated On: 09 Jun 2021 15:14:10

SAEID	USA-US062-2021-MRNA-1273-P301000013
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	TODD
Investigator's Last Name	SIMMONS
Site Address: Street	9040 FRIARS ROAD SUITE 540
Site Address: City	SAN DIEGO
Site Address: State	CA
Site Address: Postal Code	92108
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	26/MAR/2021 06:12
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3112389

Folder: SAE USA-US062-2021-MRNA-1273-P301000013

Form: Safety Report Form (2)

Data signed: (b) (4) 15 Apr 2021 23:40:44

Generated On: 09 Jun 2021 15:14:10

SAEID	USA-US062-2021-MRNA-1273-P301000013
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	TODD
Investigator's Last Name	SIMMONS
Site Address: Street	9040 FRIARS ROAD SUITE 540
Site Address: City	SAN DIEGO
Site Address: State	CA
Site Address: Postal Code	92108
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	30/MAR/2021 08:52
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3112389

Folder: SAE USA-US062-2021-MRNA-1273-P301000013

Form: Safety Report Form (3)

Data signed: (b) (4) 15 Apr 2021 23:40:44

Generated On: 09 Jun 2021 15:14:10

SAEID	USA-US062-2021-MRNA-1273-P301000013
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	TODD
Investigator's Last Name	SIMMONS
Site Address: Street	9040 FRIARS ROAD SUITE 540
Site Address: City	SAN DIEGO
Site Address: State	CA
Site Address: Postal Code	92108
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	07/APR/2021 11:32
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

US3112389

Folder: SAE USA-US062-2021-MRNA-1273-P301000013

Form: Safety Report Form (4)

Data signed: (b) (4) 15 Apr 2021 23:40:44

Generated On: 09 Jun 2021 15:14:10

SAEID	USA-US062-2021-MRNA-1273-P301000013
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	TODD
Investigator's Last Name	SIMMONS
Site Address: Street	9040 FRIARS ROAD SUITE 540
Site Address: City	SAN DIEGO
Site Address: State	CA
Site Address: Postal Code	92108
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	12/APR/2021 11:30
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

US3112389 (Prod: Medical Center For Clinical Research - M3 Wake Research)

US3112389

Form: Participant Creation

Generated On: 09 Jun 2021 15:14:10

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
User entered 'US3112389'	RWS_ENDPOINT ENDPOINT (b) (4)	26 Aug 2020 21:34:23

US3112389

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:14:10

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:26:06
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:14:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 23:02:28

US3112389

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:14:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:26:06
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:14:50
User entered '26 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	26 Aug 2020 21:34:24

US3112389

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:14:10

[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 17:26:06
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:14:50
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 23:02:28

US3112389

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:14:10

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:26:06
User entered 'SCRN'	System	26 Aug 2020 23:02:28

US3112389

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:14:10

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:26:06
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:14:50
User entered (b) (6) 1951'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	26 Aug 2020 21:34:25

US3112389

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:14:10

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:26:06
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:14:50
User entered '69'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:31:09

US3112389

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:14:10

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:26:06
User entered 'YEARS'	System	27 Aug 2020 17:31:09

US3112389

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:14:10

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:26:06
User entered '69'	System	26 Aug 2020 23:02:38

US3112389

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:14:10

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:26:06
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:14:50
User entered 'Female (F)'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:31:09

US3112389

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:14:10

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:26:06
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:14:50
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:31:09

US3112389

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:14:10

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:26:06
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:14:50
User entered 'I'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:31:09

US3112389

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:14:10

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:26:06
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:14:50
User entered '0'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:31:09

US3112389

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:14:10

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:26:06
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:14:50
User entered '0'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:31:09

US3112389

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:14:10

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:26:06
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:14:50
User entered '0'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:31:09

US3112389

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:14:10

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:26:06
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:14:50
User entered '0'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:31:09

US3112389

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:14:10

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:26:06
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:14:50
User entered '0'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:31:09

US3112389

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:14:10

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:26:06
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:14:50
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:31:09

US3112389

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:14:10

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:26:06
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:14:50
User entered '0'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:31:09

US3112389

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:14:10

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:26:06
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:14:50
User entered '0'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:31:09

US3112389

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:14:10

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:26:06
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:14:50
User entered '26 Aug 2020'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 23:02:38

US3112389

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:14:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:26:06
User entered 'Aug 2020'	System	26 Aug 2020 23:02:38

US3112389

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:14:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:26:06
User entered '2020'	System	26 Aug 2020 23:02:38

US3112389

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:14:10

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:26:06
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:14:50
User entered 'Amendment 3 (3)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 23:02:38

US3112389

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:14:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:26:06
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:14:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 23:02:38

US3112389

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:14:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:26:06
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:14:50
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 23:02:38

US3112389

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:14:10

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:26:06
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:14:50
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 23:02:38

US3112389

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:14:10

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:26:06
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:14:50
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 23:02:38

US3112389

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:14:10

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:26:06
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:14:50
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	26 Aug 2020 21:34:24

US3112389

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:14:10

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:26:06
User entered 'I'	System	26 Aug 2020 23:02:43

US3112389

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 15:14:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:26:06
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:14:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 23:02:43

US3112389

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 15:14:10

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:26:06
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:14:50
User closed query 'Per CDM: Age of the subject is >25 years. however, no medical history is collected. Please confirm or update as needed, else please clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Sep 2020 09:51:25
User entered 'Yes (Y)' reason for change: Data Entry Error	Karen Mylerberg (b) (4) (b) (4)	03 Sep 2020 00:50:04
Query 'Per CDM: Age of the subject is >25 years. however, no medical history is collected. Please confirm or update as needed, else please clarify.' answered with 'Medical history updated' (Site from DM).	Karen Mylerberg (b) (4) (b) (4)	03 Sep 2020 00:49:52
User opened query 'Per CDM: Age of the subject is >25 years. however, no medical history is collected. Please confirm or update as needed, else please clarify.' (Site from DM).	(b) (4), (b) (6)	01 Sep 2020 11:22:25
User entered 'No (N)'	(b) (4), (b) (6)	27 Aug 2020 17:35:19

US3112389

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:14:10

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:26:06
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:14:50
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Elevated cholesterol, PT: Hypercholesterolaemia, LLT: Hypercholesterolemia - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 00:52:36
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 00:52:36
Data point term sent to Coder	System	03 Sep 2020 00:51:11
User entered 'Hypercholesterolemia'	Karen Mylerberg (b) (4)	03 Sep 2020 00:50:28

US3112389

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:14:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:26:06
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:14:50
User entered 'UN UNK 2020'	Karen Mylerberg (b) (4)	03 Sep 2020 00:50:28

US3112389

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:14:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:26:06
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:14:50
User entered '0'	Karen Mylerberg (b) (4)	03 Sep 2020 00:50:28

US3112389

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:14:10

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:26:06
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:14:50
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	03 Sep 2020 00:50:28

US3112389

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:14:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:26:06
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:14:50
User entered empty.	Karen Mylerberg (b) (4)	03 Sep 2020 00:50:28

US3112389

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:14:10

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:26:06
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:14:50
User entered '0'	Karen Mylerberg (b) (4)	03 Sep 2020 00:50:28

US3112389

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:14:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:26:06
User entered 'Jan 2020'	System	03 Sep 2020 00:50:28

US3112389

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:14:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:26:06
User entered '2020'	System	03 Sep 2020 00:50:28

US3112389

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:14:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:26:06
User entered empty.	System	03 Sep 2020 00:50:28

US3112389

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:14:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:26:06
User entered empty.	System	03 Sep 2020 00:50:28

US3112389

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:14:10

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:26:06
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:14:50
User coded data point as SOC: Reproductive system and breast disorders, HLG: Menopause related conditions, HLT: Menopausal effects NEC, PT: Menopausal symptoms, LLT: Menopausal hot flashes - version MedDRA\\23.0.	Coder Import (b) (4)	10 Nov 2020 13:28:30
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	10 Nov 2020 13:28:30
Data point term sent to Coder	System	03 Sep 2020 00:52:12
User entered 'Post menopausal hot flashes'	Karen Mylerberg (b) (4)	03 Sep 2020 00:51:17

US3112389

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:14:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:26:06
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:14:50
User entered 'UN UNK 2019'	Karen Mylerberg (b) (4)	03 Sep 2020 00:51:17

US3112389

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:14:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:26:06
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:14:50
User entered '0'	Karen Mylerberg (b) (4)	03 Sep 2020 00:51:17

US3112389

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:14:10

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:26:06
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:14:50
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	03 Sep 2020 00:51:17

US3112389

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:14:10

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:26:06
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:14:50
User entered empty.	Karen Mylerberg (b) (4)	03 Sep 2020 00:51:17

US3112389

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:14:10

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:26:06
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:14:50
User entered '0'	Karen Mylerberg (b) (4)	03 Sep 2020 00:51:17

US3112389

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:14:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:26:06
User entered 'Jan 2019'	System	03 Sep 2020 00:51:17

US3112389

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:14:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:26:06
User entered '2019'	System	03 Sep 2020 00:51:17

US3112389

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:14:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:26:06
User entered empty.	System	03 Sep 2020 00:51:17

US3112389

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:14:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:26:06
User entered empty.	System	03 Sep 2020 00:51:17

US3112389

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:14:10

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:26:06
User closed query 'Per MM: Please update to provide the etiology of the mass.' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 15:08:37
Query 'Per MM: Please update to provide the etiology of the mass.' answered with 'the etiology is unknown ' (Site from DM).	Brenda Grande (b) (4)	12 Apr 2021 15:46:52
User opened query 'Per MM: Please update to provide the etiology of the mass.' (Site from DM).	(b) (4)	
User signature succeeded.	(b) (4), (b) (6)	10 Apr 2021 23:12:40
	Todd Simmons (b) (4)	09 Apr 2021 00:13:43
	(b) (4)	
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue conditions NEC, PT: Limb mass, LLT: Limb mass - version MedDRA\23.0.	Coder Import (b) (4)	07 Apr 2021 05:59:27
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	07 Apr 2021 05:59:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:34:08
	(b) (4)	
Data point term sent to Coder	System	06 Apr 2021 21:59:21
User entered 'LEFT THIGH MASS' reason for change: Data Entry Error	Matthew Musikanth	06 Apr 2021 21:58:45
	(b) (4)	
Data point term sent to Coder	System	06 Apr 2021 21:10:12
User entered 'Left thigh growth'	Matthew Musikanth	06 Apr 2021 21:09:40
	(b) (4)	

US3112389

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:14:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:26:06
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	09 Apr 2021 00:13:43
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:34:08
User entered 'UN Jun 2020' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	06 Apr 2021 21:58:45
User entered 'un Feb 2020'	Matthew Musikanth (b) (4)	06 Apr 2021 21:09:40

US3112389

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:14:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:26:06
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	09 Apr 2021 00:13:43
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:34:08
User entered '0'	Matthew Musikanth (b) (4)	06 Apr 2021 21:09:40

US3112389

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:14:10

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:26:06
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	09 Apr 2021 00:13:43
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:34:08
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	06 Apr 2021 21:09:40

US3112389

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:14:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:26:06
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	09 Apr 2021 00:13:43
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:34:08
User entered empty.	Matthew Musikanth (b) (4)	06 Apr 2021 21:09:40

US3112389

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:14:10

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:26:06
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	09 Apr 2021 00:13:43
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:34:08
User entered '0'	Matthew Musikanth (b) (4)	06 Apr 2021 21:09:40

US3112389

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:14:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:26:06
User entered 'Jun 2020'	System	06 Apr 2021 21:58:45
User entered 'Feb 2020'	System	06 Apr 2021 21:09:40

US3112389

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:14:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:26:06
User entered '2020'	System	06 Apr 2021 21:09:40

US3112389

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:14:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:26:06
User entered empty.	System	06 Apr 2021 21:09:40

US3112389

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:14:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:26:06
User entered empty.	System	06 Apr 2021 21:09:40

US3112389

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:14:10

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:26:06
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:14:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:34:12

US3112389

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:14:10

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:26:06
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:14:50
User entered '26 Aug 2020'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:34:12

US3112389

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:14:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:26:06
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:14:50
User entered '14:05'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:34:12

US3112389

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:14:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:26:06
User entered '26 Aug 2020 14:05'	System	27 Aug 2020 17:34:12

US3112389

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:14:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:26:06
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:14:50
User entered '63' in	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:34:12
DataPoint set to visible.	System	26 Aug 2020 23:02:43

US3112389

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:14:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:26:06
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:14:50
User entered '132' lb	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:34:12
DataPoint set to visible.	System	26 Aug 2020 23:02:43

US3112389

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:14:10

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:26:06
Amendment Manager: User entered '23.43164'	System	17 Sep 2020 00:04:35
User entered '23.4'	System	27 Aug 2020 17:34:12
DataPoint set to visible.	System	26 Aug 2020 23:02:43

US3112389

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:14:10

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:26:06
User entered 'kg/m2'	System	27 Aug 2020 17:34:12
DataPoint set to visible.	System	26 Aug 2020 23:02:43

US3112389

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:14:10

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:26:06
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:14:50
User closed query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly. NOTE: Route is not required.' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Sep 2020 17:54:24
Query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly. NOTE: Route is not required.' answered with 'Updated ' (Site from DM).	Karen Mylerberg (b) (4) (b) (4)	06 Sep 2020 03:33:09
User entered missing code ND - Not Done; reason for change Data Entry Error	Karen Mylerberg (b) (4) (b) (4)	06 Sep 2020 03:33:04
User opened query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly. NOTE: Route is not required.' (Site from DM).	(b) (4), (b) (6)	02 Sep 2020 12:05:39
User entered '98.5' F	(b) (4), (b) (6)	27 Aug 2020 17:34:12

US3112389

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:14:10

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:26:06
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:14:50
User entered empty; reason for change Data Entry Error	(b) (4)	
	Karen Mylerberg (b) (4)	06 Sep 2020 03:33:04
User entered 'Oral (Oral)'	(b) (4)	
	(b) (4), (b) (6)	27 Aug 2020 17:34:12

US3112389

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:14:10

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:26:06
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:14:50
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:34:12

US3112389

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:14:10

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:26:06
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:14:50
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	06 Sep 2020 03:33:04
User entered '71'	(b) (4), (b) (6)	27 Aug 2020 17:34:12

US3112389

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:14:10

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:26:06
User entered 'bpm'	System	27 Aug 2020 17:34:12

US3112389

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:14:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:26:06
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:14:50
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	06 Sep 2020 03:33:04
User entered '16'	(b) (4), (b) (6)	27 Aug 2020 17:34:12

US3112389

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:14:10

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:26:06
User entered 'breaths/min'	System	27 Aug 2020 17:34:12

US3112389

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:14:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:26:06
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:14:50
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	06 Sep 2020 03:33:04
User entered '124'	(b) (4), (b) (6)	27 Aug 2020 17:34:12

US3112389

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:14:10

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:26:06
User entered 'mmHg'	System	27 Aug 2020 17:34:12

US3112389

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:14:10

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:26:06
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:14:50
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	06 Sep 2020 03:33:04
User entered '85'	(b) (4), (b) (6)	27 Aug 2020 17:34:12

US3112389

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:14:10

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:26:06
User entered 'mmHg'	System	27 Aug 2020 17:34:12

US3112389

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:14:10

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:26:06

US3112389

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:14:10

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:26:06

US3112389

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:14:10

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:26:06
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:14:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:35:04

US3112389

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:14:10

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:26:06
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:14:50
User entered '26 Aug 2020'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:35:04

US3112389

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:14:10

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:26:06
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:14:50
User entered '26 Aug 2020'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:31:43

US3112389

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:14:10

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:26:06
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:14:50
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:31:43

US3112389

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:14:10

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:26:06
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:14:50
User entered 'Post-menopausal (POST-MENOPAUSAL)'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:31:43

US3112389

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:14:10

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:26:06
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:14:50
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:31:43

US3112389

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:14:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:26:06
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:14:50
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:31:43

US3112389

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:14:10

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:26:06
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:14:50
User entered '0'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:31:43

US3112389

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:14:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:26:06
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:14:50
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:31:43

US3112389

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:14:10

Date of last menstruation unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:26:06
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:14:50
User entered 'I'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:31:43

US3112389

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:14:10

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 17:26:06
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:14:50
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:32:40

US3112389

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:14:10

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 17:26:06
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:14:50
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:32:40

US3112389

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:14:10

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 17:26:06
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:14:50
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:32:40

US3112389

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:14:10

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 17:26:06
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:14:50
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:32:40

US3112389

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:14:10

[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 17:26:06
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:14:50
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:32:40

US3112389

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:14:10

[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 17:26:06
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:14:50
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:32:40

US3112389

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:14:10

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 17:26:06
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:14:50
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:32:40

US3112389

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:14:10

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 17:26:06
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:14:50
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:32:40

US3112389

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:14:10

[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 17:26:06
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:14:50
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:32:40

US3112389

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:14:10

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 17:26:06
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:14:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:32:40

US3112389

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:14:10

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 17:26:06
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:14:50
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:32:40

US3112389

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:14:10

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:26:06
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:14:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:32:40

US3112389

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:14:10

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:26:06
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:14:50
User entered (b) (6) Financial Professional (Frequent Airline Traveler)'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:32:40

US3112389

Folder: Screening

Form: Risk of Exposure

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No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:26:06
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:14:50
User entered '0'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:32:40

US3112389

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:14:10

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:26:06
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:14:50
User entered '0'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:32:40

US3112389

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:14:10

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 17:26:06
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:14:50
User entered '0'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:32:40

US3112389

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:14:10

[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 17:26:06
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:14:50
User entered '0'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:32:40

US3112389

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:14:10

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 17:26:06
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:14:50
User entered '0'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:32:40

US3112389

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:14:10

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:26:06
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:14:50
User entered 'I'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:32:40

US3112389

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:14:10

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:26:06
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:14:50
User entered '0'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:32:40

US3112389

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:14:10

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:26:06
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:14:50
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:32:40

US3112389

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:14:10

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 22:01:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 23:02:54

US3112389

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:14:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 22:01:20
User entered '26 Aug 2020'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 23:02:54

US3112389

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:14:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 22:01:20
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 23:02:54

US3112389

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:14:10

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User entered 'VISIT1'	System	26 Aug 2020 23:02:54

US3112389

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:14:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 22:01:20
User entered '26 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	26 Aug 2020 21:59:15

US3112389

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:14:10

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 22:01:20
User entered '188573'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	26 Aug 2020 21:59:15

US3112389

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:14:10

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 22:01:20
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	26 Aug 2020 21:59:15

US3112389

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:14:10

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)	28 Mar 2021 03:12:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 22:01:20
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:31:23

US3112389

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:14:10

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)	28 Mar 2021 03:12:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 22:01:20
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:31:23

US3112389

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:14:10

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 22:01:20
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:31:23

US3112389

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:14:10

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 22:01:20
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:31:23

US3112389

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:14:10

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 22:01:20
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:31:23

US3112389

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:14:10

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 22:01:20
User entered 'No (N)'	Karen Mylerberg (b) (4)	24 Sep 2020 14:25:49
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 08:09:22
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 08:09:21

US3112389

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:14:10

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 22:01:20
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	28 Aug 2020 15:09:48

US3112389

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:14:10

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 22:01:20
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	28 Aug 2020 15:09:48

US3112389

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:14:10

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 22:01:20
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	28 Aug 2020 15:09:48

US3112389

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:14:10

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 22:01:20
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	28 Aug 2020 15:09:48

US3112389

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:14:10

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	28 Aug 2020 15:09:48

US3112389

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:14:10

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 22:01:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Aug 2020 15:09:48

US3112389

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:14:10

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 22:01:20
User entered '26 Aug 2020'	(b) (4) (b) (4), (b) (6)	28 Aug 2020 15:09:48

US3112389

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:14:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 22:01:20
User entered '14:05'	(b) (4) (b) (4), (b) (6)	28 Aug 2020 15:09:48

US3112389

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:14:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User entered '26 Aug 2020 14:05'	System	28 Aug 2020 15:09:48

US3112389

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:14:10

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 22:01:20
User entered '98.5' F	(b) (4) (b) (4), (b) (6)	28 Aug 2020 15:09:48

US3112389

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:14:10

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 22:01:20
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	28 Aug 2020 15:09:48

US3112389

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:14:10

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 22:01:20
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Aug 2020 15:09:48

US3112389

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:14:10

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 22:01:20
User entered '71'	(b) (4) (b) (4), (b) (6)	28 Aug 2020 15:09:48

US3112389

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:14:10

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User entered 'bpm'	System	28 Aug 2020 15:09:48

US3112389

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:14:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 22:01:20
User entered '16'	(b) (4) (b) (4), (b) (6)	28 Aug 2020 15:09:48

US3112389

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:14:10

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User entered 'breaths/min'	System	28 Aug 2020 15:09:48

US3112389

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:14:10

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 22:01:20
User entered '124'	(b) (4) (b) (4), (b) (6)	28 Aug 2020 15:09:48

US3112389

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:14:10

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User entered 'mmHg'	System	28 Aug 2020 15:09:48

US3112389

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:14:10

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 22:01:20
User entered '85'	(b) (4) (b) (4), (b) (6)	28 Aug 2020 15:09:48

US3112389

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:14:10

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User entered 'mmHg'	System	28 Aug 2020 15:09:48

US3112389

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:14:10

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 22:01:20
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	28 Aug 2020 15:09:48

US3112389

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:14:10

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 22:01:20
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	28 Aug 2020 15:09:48

US3112389

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:14:10

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	28 Aug 2020 15:09:48

US3112389

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:14:10

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 22:01:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Aug 2020 15:09:48

US3112389

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:14:10

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 22:01:20
User entered '26 Aug 2020'	(b) (4) (b) (4), (b) (6)	28 Aug 2020 15:09:48

US3112389

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:14:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 22:01:20
User entered '16:05'	(b) (4) (b) (4), (b) (6)	28 Aug 2020 15:09:48

US3112389

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:14:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User entered '26 Aug 2020 16:05'	System	28 Aug 2020 15:09:48

US3112389

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:14:10

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 22:01:20
User entered '97.2' F	(b) (4) (b) (4), (b) (6)	28 Aug 2020 15:09:48

US3112389

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:14:10

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 22:01:20
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	28 Aug 2020 15:09:48

US3112389

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:14:10

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 22:01:20
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Aug 2020 15:09:48

US3112389

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:14:10

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 22:01:20
User entered '72'	(b) (4) (b) (4), (b) (6)	28 Aug 2020 15:09:48

US3112389

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:14:10

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User entered 'bpm'	System	28 Aug 2020 15:09:48

US3112389

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:14:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 22:01:20
User entered '16'	(b) (4) (b) (4), (b) (6)	28 Aug 2020 15:09:48

US3112389

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:14:10

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User entered 'breaths/min'	System	28 Aug 2020 15:09:48

US3112389

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:14:10

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 22:01:20
User entered '116'	(b) (4) (b) (4), (b) (6)	28 Aug 2020 15:09:48

US3112389

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:14:10

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User entered 'mmHg'	System	28 Aug 2020 15:09:48

US3112389

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:14:10

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 22:01:20
User entered '82'	(b) (4) (b) (4), (b) (6)	28 Aug 2020 15:09:48

US3112389

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:14:10

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User entered 'mmHg'	System	28 Aug 2020 15:09:48

US3112389

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:14:10

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 22:01:20
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:34:56

US3112389

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:14:10

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 22:01:20
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:34:56

US3112389

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:14:10

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 22:01:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 23:03:15

US3112389

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:14:10

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 22:01:20
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 23:03:15

US3112389

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:14:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 22:01:20
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 23:03:15

US3112389

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:14:10

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User entered 'MRNA-1273 OR PLACEBO'	System	26 Aug 2020 23:03:15

US3112389

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:14:10

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 22:01:20
User entered '26 Aug 2020'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 23:03:15

US3112389

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:14:10

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 22:01:20
User entered '15:34'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 23:03:15

US3112389

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:14:10

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User entered '26 Aug 2020 15:34'	System	26 Aug 2020 23:03:15

US3112389

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:14:10

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 22:01:20
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 23:03:15

US3112389

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:14:10

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User entered 'ONCE'	System	26 Aug 2020 23:03:15

US3112389

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:14:10

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User entered 'INTRAMUSCULAR'	System	26 Aug 2020 23:03:15

US3112389

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:14:10

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 22:01:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:34:35

US3112389

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:14:10

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 22:01:20
User entered '26 Aug 2020'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:34:35

US3112389

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:14:10

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 22:01:20
User entered '15:09'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:34:35

US3112389

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:14:10

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User entered '26 Aug 2020 15:09'	System	27 Aug 2020 17:34:35

US3112389

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:14:10

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 22:01:20
User entered '26 Aug 2020'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:34:47

US3112389

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:14:10

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	27 Aug 2020 17:34:47

US3112389

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:14:10

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 22:01:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:34:47

US3112389

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:14:10

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 22:01:20
User entered '14:48'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:34:47

US3112389

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:14:10

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User entered '26 Aug 2020 14:48'	System	27 Aug 2020 17:34:47

US3112389

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:14:10

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	27 Aug 2020 17:34:47

US3112389

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:14:10

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 22:01:20
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:34:47

US3112389

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:14:10

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 22:01:20
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:34:47

US3112389

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:14:10

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User entered empty.	System	27 Aug 2020 17:34:47

US3112389

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:14:10

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 22:01:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 23:03:22

US3112389

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:14:10

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User entered 'I'	System	26 Aug 2020 23:03:22

US3112389

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
Data entry locked.	System	26 Aug 2020 23:03:15
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	26 Aug 2020 23:03:15

US3112389

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:14:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-08-26T16:06:10', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '0e40d670-f9aa-459e-a738-8fbf3151ef12' User entered 'Yes (Y)'	System	26 Aug 2020 23:06:38
	System	26 Aug 2020 23:06:38

US3112389

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:14:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-08-26T16:06:20', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '0e40d670-f9aa-459e-a738-8fbf3151ef12' User entered '97.2'	System	26 Aug 2020 23:06:38
	System	26 Aug 2020 23:06:38

US3112389

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:14:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-08-26T16:06:25', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '0e40d670-f9aa-459e-a738-8fbf3151ef12'	System	26 Aug 2020 23:06:38
User entered 'No (N)'	System	26 Aug 2020 23:06:38

US3112389

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:14:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-08-26T16:06:33', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '0e40d670-f9aa-459e-a738-8fbf3151ef12' User entered '26 Aug 2020 16:06'	System	26 Aug 2020 23:06:38
	System	26 Aug 2020 23:06:38

US3112389

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:14:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
User entered '26 Aug 2020 15:54'	System	26 Aug 2020 23:03:15

US3112389

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:14:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
User entered '26 Aug 2020 18:24'	System	26 Aug 2020 23:03:15

US3112389

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
Data entry locked.	System	26 Aug 2020 23:03:15
User entered 'Day 1, after vaccination (at home)'	System	26 Aug 2020 23:03:15

US3112389

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:14:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-08-27T00:31:32', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '8c9c3d89-79ed-4a43-a13c-d33f74bf77b5' User entered 'Yes (Y)'	System	27 Aug 2020 07:31:57
	System	27 Aug 2020 07:31:57

US3112389

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:14:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-08-27T00:31:39', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '8c9c3d89-79ed-4a43-a13c-d33f74bf77b5' User entered '97.5'	System	27 Aug 2020 07:31:57
	System	27 Aug 2020 07:31:57

US3112389

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:14:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-08-27T00:31:46', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '8c9c3d89-79ed-4a43-a13c-d33f74bf77b5'	System	27 Aug 2020 07:31:57
User entered 'No (N)'	System	27 Aug 2020 07:31:57

US3112389

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:14:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-08-27T00:31:53', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '8c9c3d89-79ed-4a43-a13c-d33f74bf77b5' User entered '27 Aug 2020 00:31'	System	27 Aug 2020 07:31:57
	System	27 Aug 2020 07:31:57

US3112389

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:14:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
User entered '26 Aug 2020 19:19'	System	26 Aug 2020 23:03:15

US3112389

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:14:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
User entered '27 Aug 2020 11:59'	System	26 Aug 2020 23:03:15

US3112389

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
Data entry locked.	System	26 Aug 2020 23:03:15
User entered 'Day 2'	System	26 Aug 2020 23:03:15

US3112389

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:14:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-08-27T17:45:11', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '7673eb95-5ca3-49f3-9ff5-cb4df8df64ac'	System	28 Aug 2020 00:45:54
User entered 'Yes (Y)'	System	28 Aug 2020 00:45:54

US3112389

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:14:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-08-27T17:45:35', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '7673eb95-5ca3-49f3-9ff5-cb4df8df64ac' User entered '97.1'	System	28 Aug 2020 00:45:54
	System	28 Aug 2020 00:45:54

US3112389

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:14:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-08-27T17:45:44', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '7673eb95-5ca3-49f3-9ff5-cb4df8df64ac'	System	28 Aug 2020 00:45:54
User entered 'No (N)'	System	28 Aug 2020 00:45:54

US3112389

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:14:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-08-27T17:45:50', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '7673eb95-5ca3-49f3-9ff5-cb4df8df64ac' User entered '27 Aug 2020 17:45'	System	28 Aug 2020 00:45:54
	System	28 Aug 2020 00:45:54

US3112389

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:14:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
User entered '27 Aug 2020 12:00'	System	26 Aug 2020 23:03:15

US3112389

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:14:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
User entered '28 Aug 2020 11:59'	System	26 Aug 2020 23:03:15

US3112389

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
Data entry locked.	System	26 Aug 2020 23:03:15
User entered 'Day 3'	System	26 Aug 2020 23:03:15

US3112389

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:14:10

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-08-29T00:06:32', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: 'bcb08fa5-a07b-41ce-95ea-ad0e4d55796d' User entered 'Yes (Y)'	System	29 Aug 2020 07:06:56
	System	29 Aug 2020 07:06:56

US3112389

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:14:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-08-29T00:06:43', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: 'bcb08fa5-a07b-41ce-95ea-ad0e4d55796d' User entered '96.6'	System	29 Aug 2020 07:06:56
	System	29 Aug 2020 07:06:56

US3112389

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:14:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-08-29T00:06:49', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: 'bcb08fa5-a07b-41ce-95ea-ad0e4d55796d' User entered 'No (N)'	System	29 Aug 2020 07:06:56
	System	29 Aug 2020 07:06:56

US3112389

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:14:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-08-29T00:06:55', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: 'bcb08fa5-a07b-41ce-95ea-ad0e4d55796d' User entered '29 Aug 2020 00:06'	System	29 Aug 2020 07:06:56
	System	29 Aug 2020 07:06:56

US3112389

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:14:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
User entered '28 Aug 2020 12:00'	System	26 Aug 2020 23:03:15

US3112389

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:14:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
User entered '29 Aug 2020 11:59'	System	26 Aug 2020 23:03:15

US3112389

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
Data entry locked.	System	26 Aug 2020 23:03:15
User entered 'Day 4'	System	26 Aug 2020 23:03:15

US3112389

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:14:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-08-30T00:56:34', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: 'a890f6a2-3c0d-4e8f-bc25-1da814070e51' User entered 'Yes (Y)'	System	30 Aug 2020 07:57:25
	System	30 Aug 2020 07:57:25

US3112389

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:14:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-08-30T00:56:54', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: 'a890f6a2-3c0d-4e8f-bc25-1da814070e51' User entered '95.6'	System	30 Aug 2020 07:57:25
	System	30 Aug 2020 07:57:25

US3112389

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:14:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-08-30T00:57:11', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: 'a890f6a2-3c0d-4e8f-bc25-1da814070e51'	System	30 Aug 2020 07:57:25
User entered 'No (N)'	System	30 Aug 2020 07:57:25

US3112389

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:14:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-08-30T00:57:21', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: 'a890f6a2-3c0d-4e8f-bc25-1da814070e51' User entered '30 Aug 2020 00:57'	System	30 Aug 2020 07:57:25
	System	30 Aug 2020 07:57:25

US3112389

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:14:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
User entered '29 Aug 2020 12:00'	System	26 Aug 2020 23:03:15

US3112389

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:14:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
User entered '30 Aug 2020 11:59'	System	26 Aug 2020 23:03:15

US3112389

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
Data entry locked.	System	26 Aug 2020 23:03:15
User entered 'Day 5'	System	26 Aug 2020 23:03:15

US3112389

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:14:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-08-30T22:13:09', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '97e56fd1-ad74-4ae9-bf87-61262f6ebc2c' User entered 'Yes (Y)'	System	31 Aug 2020 05:13:30
	System	31 Aug 2020 05:13:30

US3112389

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:14:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-08-30T22:13:16', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '97e56fd1-ad74-4ae9-bf87-61262f6ebc2c' User entered '96.3'	System	31 Aug 2020 05:13:30
	System	31 Aug 2020 05:13:30

US3112389

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:14:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-08-30T22:13:22', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '97e56fd1-ad74-4ae9-bf87-61262f6ebc2c'	System	31 Aug 2020 05:13:30
User entered 'No (N)'	System	31 Aug 2020 05:13:30

US3112389

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:14:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-08-30T22:13:28', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '97e56fd1-ad74-4ae9-bf87-61262f6ebc2c' User entered '30 Aug 2020 22:13'	System	31 Aug 2020 05:13:30
	System	31 Aug 2020 05:13:30

US3112389

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:14:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
User entered '30 Aug 2020 12:00'	System	26 Aug 2020 23:03:15

US3112389

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:14:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
User entered '31 Aug 2020 11:59'	System	26 Aug 2020 23:03:15

US3112389

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
Data entry locked.	System	26 Aug 2020 23:03:15
User entered 'Day 6'	System	26 Aug 2020 23:03:15

US3112389

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:14:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-08-31T23:52:56', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: 'eef311e0-d919-45b8-9fca-08b166062ba5' User entered 'Yes (Y)'	System	01 Sep 2020 06:53:26
	System	01 Sep 2020 06:53:26

US3112389

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:14:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-08-31T23:53:13', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: 'eef311e0-d919-45b8-9fca-08b166062ba5' User entered '95.3'	System	01 Sep 2020 06:53:26
	System	01 Sep 2020 06:53:26

US3112389

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:14:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-08-31T23:53:17', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: 'eef311e0-d919-45b8-9fca-08b166062ba5' User entered 'No (N)'	System	01 Sep 2020 06:53:26
	System	01 Sep 2020 06:53:26

US3112389

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:14:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-08-31T23:53:23', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: 'eef311e0-d919-45b8-9fca-08b166062ba5' User entered '31 Aug 2020 23:53'	System	01 Sep 2020 06:53:26
	System	01 Sep 2020 06:53:26

US3112389

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:14:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
User entered '31 Aug 2020 12:00'	System	26 Aug 2020 23:03:15

US3112389

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:14:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
User entered '01 Sep 2020 11:59'	System	26 Aug 2020 23:03:15

US3112389

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
Data entry locked.	System	26 Aug 2020 23:03:15
User entered 'Day 7'	System	26 Aug 2020 23:03:15

US3112389

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:14:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-09-01T21:02:04', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: 'db8f71df-0afd-4a9d-aabc-6aad111c4375'	System	02 Sep 2020 04:02:20
User entered 'Yes (Y)'	System	02 Sep 2020 04:02:20

US3112389

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:14:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-09-01T21:02:10', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: 'db8f71df-0afd-4a9d-aabc-6aad111c4375' User entered '97.0'	System	02 Sep 2020 04:02:20
	System	02 Sep 2020 04:02:20

US3112389

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:14:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-09-01T21:02:13', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: 'db8f71df-0afd-4a9d-aabc-6aad111c4375'	System	02 Sep 2020 04:02:20
User entered 'No (N)'	System	02 Sep 2020 04:02:20

US3112389

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:14:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-09-01T21:02:18', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: 'db8f71df-0afd-4a9d-aabc-6aad111c4375'	System	02 Sep 2020 04:02:20
User entered '01 Sep 2020 21:02'	System	02 Sep 2020 04:02:20

US3112389

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:14:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
User entered '01 Sep 2020 12:00'	System	26 Aug 2020 23:03:15

US3112389

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:14:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
User entered '02 Sep 2020 11:59'	System	26 Aug 2020 23:03:15

US3112389

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
Data entry locked.	System	26 Aug 2020 23:03:15
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	26 Aug 2020 23:03:15

US3112389

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:14:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-08-26T16:06:57', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '929c54f3-19d6-48f4-8b76-d4f0a5c18a4d' User entered 'None (1)'	System	26 Aug 2020 23:07:41
	System	26 Aug 2020 23:07:41

US3112389

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:14:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-08-26T16:07:03', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '929c54f3-19d6-48f4-8b76-d4f0a5c18a4d' User entered 'No (N)'	System	26 Aug 2020 23:07:41
	System	26 Aug 2020 23:07:41

US3112389

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:14:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-08-26T16:07:08', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '929c54f3-19d6-48f4-8b76-d4f0a5c18a4d' User entered 'No (N)'	System	26 Aug 2020 23:07:41
	System	26 Aug 2020 23:07:41

US3112389

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:14:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-08-26T16:07:32', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '929c54f3-19d6-48f4-8b76-d4f0a5c18a4d' User entered 'None (1)'	System	26 Aug 2020 23:07:41
	System	26 Aug 2020 23:07:41

US3112389

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:14:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-08-26T16:07:39', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '929c54f3-19d6-48f4-8b76-d4f0a5c18a4d' User entered '26 Aug 2020 16:07'	System	26 Aug 2020 23:07:41
	System	26 Aug 2020 23:07:41

US3112389

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:14:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
User entered '26 Aug 2020 15:54'	System	26 Aug 2020 23:03:15

US3112389

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:14:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
User entered '26 Aug 2020 18:24'	System	26 Aug 2020 23:03:15

US3112389

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
Data entry locked.	System	26 Aug 2020 23:03:15
User entered 'Day 1, after vaccination (at home)'	System	26 Aug 2020 23:03:15

US3112389

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:14:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-08-27T00:32:07', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '0d428350-a9dc-4bcf-a8a0-0880eea1b810' User entered 'None (1)'	System	27 Aug 2020 07:33:07
	System	27 Aug 2020 07:33:07

US3112389

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:14:10

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-08-27T00:32:23', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '0d428350-a9dc-4bcf-a8a0-0880eea1b810' User entered 'No (N)'	System	27 Aug 2020 07:33:07
	System	27 Aug 2020 07:33:07

US3112389

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:14:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-08-27T00:32:34', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '0d428350-a9dc-4bcf-a8a0-0880eea1b810' User entered 'No (N)'	System	27 Aug 2020 07:33:07
	System	27 Aug 2020 07:33:07

US3112389

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:14:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-08-27T00:32:57', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '0d428350-a9dc-4bcf-a8a0-0880eea1b810' User entered 'None (1)'	System	27 Aug 2020 07:33:07
	System	27 Aug 2020 07:33:07

US3112389

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:14:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-08-27T00:33:05', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '0d428350-a9dc-4bcf-a8a0-0880eea1b810' User entered '27 Aug 2020 00:33'	System	27 Aug 2020 07:33:07
	System	27 Aug 2020 07:33:07

US3112389

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:14:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
User entered '26 Aug 2020 19:19'	System	26 Aug 2020 23:03:15

US3112389

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:14:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
User entered '27 Aug 2020 11:59'	System	26 Aug 2020 23:03:15

US3112389

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
Data entry locked.	System	26 Aug 2020 23:03:15
User entered 'Day 2'	System	26 Aug 2020 23:03:15

US3112389

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:14:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-08-27T17:46:06', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '80087b41-2dc3-4c43-92af-f2fde25256f7'	System	28 Aug 2020 00:47:01
User entered 'Does not interfere with activity (2)'	System	28 Aug 2020 00:47:01

US3112389

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:14:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-08-27T17:46:15', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '80087b41-2dc3-4c43-92af-f2fde25256f7'	System	28 Aug 2020 00:47:01
User entered 'No (N)'	System	28 Aug 2020 00:47:01

US3112389

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:14:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-08-27T17:46:27', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '80087b41-2dc3-4c43-92af-f2fde25256f7' User entered 'No (N)'	System	28 Aug 2020 00:47:01
	System	28 Aug 2020 00:47:01

US3112389

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:14:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-08-27T17:46:47', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '80087b41-2dc3-4c43-92af-f2fde25256f7'	System	28 Aug 2020 00:47:01
User entered 'None (1)'	System	28 Aug 2020 00:47:01

US3112389

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:14:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-08-27T17:46:59', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '80087b41-2dc3-4c43-92af-f2fde25256f7' User entered '27 Aug 2020 17:46'	System	28 Aug 2020 00:47:01
	System	28 Aug 2020 00:47:01

US3112389

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:14:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
User entered '27 Aug 2020 12:00'	System	26 Aug 2020 23:03:15

US3112389

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:14:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
User entered '28 Aug 2020 11:59'	System	26 Aug 2020 23:03:15

US3112389

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
Data entry locked.	System	26 Aug 2020 23:03:15
User entered 'Day 3'	System	26 Aug 2020 23:03:15

US3112389

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:14:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-08-29T00:07:09', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '0b901a18-4ca5-44bf-824d-79312bba92e3'	System	29 Aug 2020 07:07:57
User entered 'Does not interfere with activity (2)'	System	29 Aug 2020 07:07:57

US3112389

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:14:10

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-08-29T00:07:13', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '0b901a18-4ca5-44bf-824d-79312bba92e3' User entered 'No (N)'	System	29 Aug 2020 07:07:57
	System	29 Aug 2020 07:07:57

US3112389

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:14:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-08-29T00:07:24', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '0b901a18-4ca5-44bf-824d-79312bba92e3' User entered 'No (N)'	System	29 Aug 2020 07:07:57
	System	29 Aug 2020 07:07:57

US3112389

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:14:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-08-29T00:07:46', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '0b901a18-4ca5-44bf-824d-79312bba92e3' User entered 'None (1)'	System	29 Aug 2020 07:07:57
	System	29 Aug 2020 07:07:57

US3112389

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:14:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-08-29T00:07:52', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '0b901a18-4ca5-44bf-824d-79312bba92e3' User entered '29 Aug 2020 00:07'	System	29 Aug 2020 07:07:57
	System	29 Aug 2020 07:07:57

US3112389

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:14:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
User entered '28 Aug 2020 12:00'	System	26 Aug 2020 23:03:15

US3112389

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:14:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
User entered '29 Aug 2020 11:59'	System	26 Aug 2020 23:03:15

US3112389

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
Data entry locked.	System	26 Aug 2020 23:03:15
User entered 'Day 4'	System	26 Aug 2020 23:03:15

US3112389

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:14:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-08-30T00:58:04', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '9a7743ff-256a-4858-aff4-b3c8eb4c2865'	System	30 Aug 2020 07:58:52
User entered 'Does not interfere with activity (2)'	System	30 Aug 2020 07:58:52

US3112389

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:14:10

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-08-30T00:58:11', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '9a7743ff-256a-4858-aff4-b3c8eb4c2865'	System	30 Aug 2020 07:58:52
User entered 'No (N)'	System	30 Aug 2020 07:58:52

US3112389

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:14:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-08-30T00:58:17', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '9a7743ff-256a-4858-aff4-b3c8eb4c2865' User entered 'No (N)'	System	30 Aug 2020 07:58:52
	System	30 Aug 2020 07:58:52

US3112389

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:14:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-08-30T00:58:31', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '9a7743ff-256a-4858-aff4-b3c8eb4c2865'	System	30 Aug 2020 07:58:52
User entered 'None (1)'	System	30 Aug 2020 07:58:52

US3112389

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:14:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-08-30T00:58:48', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '9a7743ff-256a-4858-aff4-b3c8eb4c2865' User entered '30 Aug 2020 00:58'	System	30 Aug 2020 07:58:52
	System	30 Aug 2020 07:58:52

US3112389

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:14:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
User entered '29 Aug 2020 12:00'	System	26 Aug 2020 23:03:15

US3112389

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:14:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
User entered '30 Aug 2020 11:59'	System	26 Aug 2020 23:03:15

US3112389

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
Data entry locked.	System	26 Aug 2020 23:03:15
User entered 'Day 5'	System	26 Aug 2020 23:03:15

US3112389

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:14:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-08-30T22:13:43', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: 'fe39b654-5b92-4671-9a1b-b44b996f379f'	System	31 Aug 2020 05:14:14
User entered 'Does not interfere with activity (2)'	System	31 Aug 2020 05:14:14

US3112389

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:14:10

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-08-30T22:13:51', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: 'fe39b654-5b92-4671-9a1b-b44b996f379f' User entered 'No (N)'	System	31 Aug 2020 05:14:14
	System	31 Aug 2020 05:14:14

US3112389

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:14:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-08-30T22:13:55', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: 'fe39b654-5b92-4671-9a1b-b44b996f379f' User entered 'No (N)'	System	31 Aug 2020 05:14:14
	System	31 Aug 2020 05:14:14

US3112389

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:14:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-08-30T22:14:05', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: 'fe39b654-5b92-4671-9a1b-b44b996f379f' User entered 'None (1)'	System	31 Aug 2020 05:14:14
	System	31 Aug 2020 05:14:14

US3112389

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:14:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-08-30T22:14:12', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: 'fe39b654-5b92-4671-9a1b-b44b996f379f' User entered '30 Aug 2020 22:14'	System	31 Aug 2020 05:14:14
	System	31 Aug 2020 05:14:14

US3112389

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:14:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
User entered '30 Aug 2020 12:00'	System	26 Aug 2020 23:03:15

US3112389

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:14:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
User entered '31 Aug 2020 11:59'	System	26 Aug 2020 23:03:15

US3112389

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
Data entry locked.	System	26 Aug 2020 23:03:15
User entered 'Day 6'	System	26 Aug 2020 23:03:15

US3112389

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:14:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-08-31T23:53:31', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '0a510866-c53e-4e9e-aaa8-607328aa725a' User entered 'None (1)'	System	01 Sep 2020 06:53:51
	System	01 Sep 2020 06:53:51

US3112389

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:14:10

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-08-31T23:53:35', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '0a510866-c53e-4e9e-aaa8-607328aa725a' User entered 'No (N)'	System	01 Sep 2020 06:53:51
	System	01 Sep 2020 06:53:51

US3112389

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:14:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-08-31T23:53:38', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '0a510866-c53e-4e9e-aaa8-607328aa725a' User entered 'No (N)'	System	01 Sep 2020 06:53:51
	System	01 Sep 2020 06:53:51

US3112389

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:14:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-08-31T23:53:43', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '0a510866-c53e-4e9e-aaa8-607328aa725a' User entered 'None (1)'	System	01 Sep 2020 06:53:51
	System	01 Sep 2020 06:53:51

US3112389

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:14:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-08-31T23:53:48', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '0a510866-c53e-4e9e-aaa8-607328aa725a' User entered '31 Aug 2020 23:53'	System	01 Sep 2020 06:53:51
	System	01 Sep 2020 06:53:51

US3112389

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:14:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
User entered '31 Aug 2020 12:00'	System	26 Aug 2020 23:03:15

US3112389

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:14:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
User entered '01 Sep 2020 11:59'	System	26 Aug 2020 23:03:15

US3112389

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
Data entry locked.	System	26 Aug 2020 23:03:15
User entered 'Day 7'	System	26 Aug 2020 23:03:15

US3112389

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:14:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-09-01T21:02:44', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: 'a38c5710-dddb-4620-9a5e-e6777cb94ef4'	System	02 Sep 2020 04:03:19
User entered 'None (1)'	System	02 Sep 2020 04:03:19

US3112389

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:14:10

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-09-01T21:02:47', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: 'a38c5710-dddb-4620-9a5e-e6777cb94ef4' User entered 'No (N)'	System	02 Sep 2020 04:03:19
	System	02 Sep 2020 04:03:19

US3112389

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:14:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-09-01T21:02:51', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: 'a38c5710-dddb-4620-9a5e-e6777cb94ef4' User entered 'No (N)'	System	02 Sep 2020 04:03:19
	System	02 Sep 2020 04:03:19

US3112389

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:14:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-09-01T21:02:54', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: 'a38c5710-dddb-4620-9a5e-e6777cb94ef4'	System	02 Sep 2020 04:03:19
User entered 'None (1)'	System	02 Sep 2020 04:03:19

US3112389

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:14:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-09-01T21:03:13', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: 'a38c5710-dddb-4620-9a5e-e6777cb94ef4' User entered '01 Sep 2020 21:03'	System	02 Sep 2020 04:03:19
	System	02 Sep 2020 04:03:19

US3112389

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:14:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
User entered '01 Sep 2020 12:00'	System	26 Aug 2020 23:03:15

US3112389

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:14:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
User entered '02 Sep 2020 11:59'	System	26 Aug 2020 23:03:15

US3112389

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
Data entry locked.	System	26 Aug 2020 23:03:15
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	26 Aug 2020 23:03:15

US3112389

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:14:10

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-08-26T16:07:50', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: 'b177c151-b1e2-4517-a263-c9853a824f49' User entered 'None (0)'	System	26 Aug 2020 23:08:27
	System	26 Aug 2020 23:08:27

US3112389

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:14:10

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-08-26T16:08:00', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: 'b177c151-b1e2-4517-a263-c9853a824f49' User entered 'None (0)'	System	26 Aug 2020 23:08:27
	System	26 Aug 2020 23:08:27

US3112389

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:14:10

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-08-26T16:08:03', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: 'b177c151-b1e2-4517-a263-c9853a824f49' User entered 'None (0)'	System	26 Aug 2020 23:08:27
	System	26 Aug 2020 23:08:27

US3112389

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:14:10

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-08-26T16:08:08', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: 'b177c151-b1e2-4517-a263-c9853a824f49' User entered 'None (0)'	System	26 Aug 2020 23:08:27
	System	26 Aug 2020 23:08:27

US3112389

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:14:10

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-08-26T16:08:10', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: 'b177c151-b1e2-4517-a263-c9853a824f49' User entered 'None (0)'	System	26 Aug 2020 23:08:27
	System	26 Aug 2020 23:08:27

US3112389

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:14:10

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-08-26T16:08:13', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: 'b177c151-b1e2-4517-a263-c9853a824f49' User entered 'None (0)'	System	26 Aug 2020 23:08:27
	System	26 Aug 2020 23:08:27

US3112389

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:14:10

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)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-08-26T16:08:20', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: 'b177c151-b1e2-4517-a263-c9853a824f49' User entered 'No (N)'	System	26 Aug 2020 23:08:27
	System	26 Aug 2020 23:08:27

US3112389

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:14:10

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-08-26T16:08:25', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: 'b177c151-b1e2-4517-a263-c9853a824f49' User entered '26 Aug 2020 16:08'	System	26 Aug 2020 23:08:27
	System	26 Aug 2020 23:08:27

US3112389

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:14:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
User entered '26 Aug 2020 15:54'	System	26 Aug 2020 23:03:15

US3112389

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:14:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
User entered '26 Aug 2020 18:24'	System	26 Aug 2020 23:03:15

US3112389

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
Data entry locked.	System	26 Aug 2020 23:03:15
User entered 'Day 1, after vaccination (at home)'	System	26 Aug 2020 23:03:15

US3112389

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:14:10

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-08-27T00:33:18', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '42cf25c9-76fe-4ae2-bd77-06b6a6a28677' User entered 'None (0)'	System	27 Aug 2020 07:34:36
	System	27 Aug 2020 07:34:36

US3112389

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:14:10

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-08-27T00:33:30', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '42cf25c9-76fe-4ae2-bd77-06b6a6a28677' User entered 'None (0)'	System	27 Aug 2020 07:34:36
	System	27 Aug 2020 07:34:36

US3112389

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:14:10

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-08-27T00:33:38', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '42cf25c9-76fe-4ae2-bd77-06b6a6a28677' User entered 'None (0)'	System	27 Aug 2020 07:34:36
	System	27 Aug 2020 07:34:36

US3112389

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:14:10

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-08-27T00:33:53', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '42cf25c9-76fe-4ae2-bd77-06b6a6a28677' User entered 'None (0)'	System	27 Aug 2020 07:34:36
	System	27 Aug 2020 07:34:36

US3112389

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:14:10

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-08-27T00:34:07', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '42cf25c9-76fe-4ae2-bd77-06b6a6a28677' User entered 'None (0)'	System	27 Aug 2020 07:34:36
	System	27 Aug 2020 07:34:36

US3112389

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:14:10

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-08-27T00:34:14', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '42cf25c9-76fe-4ae2-bd77-06b6a6a28677' User entered 'None (0)'	System	27 Aug 2020 07:34:36
	System	27 Aug 2020 07:34:36

US3112389

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:14:10

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)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-08-27T00:34:27', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '42cf25c9-76fe-4ae2-bd77-06b6a6a28677'	System	27 Aug 2020 07:34:36
User entered 'No (N)'	System	27 Aug 2020 07:34:36

US3112389

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:14:10

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-08-27T00:34:34', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '42cf25c9-76fe-4ae2-bd77-06b6a6a28677' User entered '27 Aug 2020 00:34'	System	27 Aug 2020 07:34:36
	System	27 Aug 2020 07:34:36

US3112389

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:14:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
User entered '26 Aug 2020 19:19'	System	26 Aug 2020 23:03:15

US3112389

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:14:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
User entered '27 Aug 2020 11:59'	System	26 Aug 2020 23:03:15

US3112389

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
Data entry locked.	System	26 Aug 2020 23:03:15
User entered 'Day 2'	System	26 Aug 2020 23:03:15

US3112389

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:14:10

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-08-27T17:47:10', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: 'bebe6370-b135-4b9e-8b3a-d956760e89b7' User entered 'None (0)'	System	28 Aug 2020 00:48:24
	System	28 Aug 2020 00:48:24

US3112389

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:14:10

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-08-27T17:47:25', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: 'bebe6370-b135-4b9e-8b3a-d956760e89b7'	System	28 Aug 2020 00:48:24
User entered 'No interference with activity (1)'	System	28 Aug 2020 00:48:24

US3112389

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:14:10

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-08-27T17:47:39', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: 'bebe6370-b135-4b9e-8b3a-d956760e89b7' User entered 'None (0)'	System	28 Aug 2020 00:48:24
	System	28 Aug 2020 00:48:24

US3112389

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:14:10

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-08-27T17:47:49', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: 'bebe6370-b135-4b9e-8b3a-d956760e89b7' User entered 'None (0)'	System	28 Aug 2020 00:48:24
	System	28 Aug 2020 00:48:24

US3112389

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:14:10

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-08-27T17:47:56', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: 'bebe6370-b135-4b9e-8b3a-d956760e89b7' User entered 'None (0)'	System	28 Aug 2020 00:48:24
	System	28 Aug 2020 00:48:24

US3112389

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:14:10

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-08-27T17:48:00', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: 'bebe6370-b135-4b9e-8b3a-d956760e89b7' User entered 'None (0)'	System	28 Aug 2020 00:48:24
	System	28 Aug 2020 00:48:24

US3112389

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:14:10

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)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-08-27T17:48:07', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: 'bebe6370-b135-4b9e-8b3a-d956760e89b7'	System	28 Aug 2020 00:48:24
User entered 'No (N)'	System	28 Aug 2020 00:48:24

US3112389

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:14:10

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-08-27T17:48:18', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: 'bebe6370-b135-4b9e-8b3a-d956760e89b7' User entered '27 Aug 2020 17:48'	System	28 Aug 2020 00:48:24
	System	28 Aug 2020 00:48:24

US3112389

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:14:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
User entered '27 Aug 2020 12:00'	System	26 Aug 2020 23:03:15

US3112389

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:14:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
User entered '28 Aug 2020 11:59'	System	26 Aug 2020 23:03:15

US3112389

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
Data entry locked.	System	26 Aug 2020 23:03:15
User entered 'Day 3'	System	26 Aug 2020 23:03:15

US3112389

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:14:10

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-08-29T00:08:05', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '11dba426-f8c5-4030-a47c-ec9cf15c8860'	System	29 Aug 2020 07:09:44
User entered 'No interference with activity (1)'	System	29 Aug 2020 07:09:44

US3112389

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:14:10

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-08-29T00:09:35', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '11dba426-f8c5-4030-a47c-ec9cf15c8860'	System	29 Aug 2020 07:09:44
User entered 'Some interference with activity (2)'	System	29 Aug 2020 07:09:44

US3112389

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:14:10

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-08-29T00:08:30', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '11dba426-f8c5-4030-a47c-ec9cf15c8860'	System	29 Aug 2020 07:09:44
User entered 'No interference with activity (1)'	System	29 Aug 2020 07:09:44

US3112389

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:14:10

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-08-29T00:08:35', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '11dba426-f8c5-4030-a47c-ec9cf15c8860' User entered 'None (0)'	System	29 Aug 2020 07:09:44
	System	29 Aug 2020 07:09:44

US3112389

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:14:10

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-08-29T00:08:49', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '11dba426-f8c5-4030-a47c-ec9cf15c8860' User entered 'None (0)'	System	29 Aug 2020 07:09:44
	System	29 Aug 2020 07:09:44

US3112389

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:14:10

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-08-29T00:08:56', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '11dba426-f8c5-4030-a47c-ec9cf15c8860' User entered 'None (0)'	System	29 Aug 2020 07:09:44
	System	29 Aug 2020 07:09:44

US3112389

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:14:10

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)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-08-29T00:09:03', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '11dba426-f8c5-4030-a47c-ec9cf15c8860' User entered 'No (N)'	System	29 Aug 2020 07:09:44
	System	29 Aug 2020 07:09:44

US3112389

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:14:10

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-08-29T00:09:40', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '11dba426-f8c5-4030-a47c-ec9cf15c8860' User entered '29 Aug 2020 00:09'	System	29 Aug 2020 07:09:44
	System	29 Aug 2020 07:09:44

US3112389

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:14:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
User entered '28 Aug 2020 12:00'	System	26 Aug 2020 23:03:15

US3112389

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:14:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
User entered '29 Aug 2020 11:59'	System	26 Aug 2020 23:03:15

US3112389

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
Data entry locked.	System	26 Aug 2020 23:03:15
User entered 'Day 4'	System	26 Aug 2020 23:03:15

US3112389

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:14:10

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-08-30T00:59:08', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '9b3c3fe8-add1-46d7-9222-e18d4137856d' User entered 'None (0)'	System	30 Aug 2020 08:00:17
	System	30 Aug 2020 08:00:17

US3112389

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:14:10

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-08-30T00:59:19', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '9b3c3fe8-add1-46d7-9222-e18d4137856d'	System	30 Aug 2020 08:00:17
User entered 'No interference with activity (1)'	System	30 Aug 2020 08:00:17

US3112389

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:14:10

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-08-30T00:59:27', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '9b3c3fe8-add1-46d7-9222-e18d4137856d' User entered 'None (0)'	System	30 Aug 2020 08:00:17
	System	30 Aug 2020 08:00:17

US3112389

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:14:10

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-08-30T00:59:31', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '9b3c3fe8-add1-46d7-9222-e18d4137856d' User entered 'None (0)'	System	30 Aug 2020 08:00:17
	System	30 Aug 2020 08:00:17

US3112389

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:14:10

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-08-30T00:59:45', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '9b3c3fe8-add1-46d7-9222-e18d4137856d' User entered 'None (0)'	System	30 Aug 2020 08:00:17
	System	30 Aug 2020 08:00:17

US3112389

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:14:10

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-08-30T00:59:49', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '9b3c3fe8-add1-46d7-9222-e18d4137856d' User entered 'None (0)'	System	30 Aug 2020 08:00:17
	System	30 Aug 2020 08:00:17

US3112389

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:14:10

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)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-08-30T00:59:57', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '9b3c3fe8-add1-46d7-9222-e18d4137856d' User entered 'No (N)'	System	30 Aug 2020 08:00:17
	System	30 Aug 2020 08:00:17

US3112389

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:14:10

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-08-30T01:00:15', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '9b3c3fe8-add1-46d7-9222-e18d4137856d' User entered '30 Aug 2020 01:00'	System	30 Aug 2020 08:00:17
	System	30 Aug 2020 08:00:17

US3112389

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:14:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
User entered '29 Aug 2020 12:00'	System	26 Aug 2020 23:03:15

US3112389

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:14:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
User entered '30 Aug 2020 11:59'	System	26 Aug 2020 23:03:15

US3112389

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
Data entry locked.	System	26 Aug 2020 23:03:15
User entered 'Day 5'	System	26 Aug 2020 23:03:15

US3112389

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:14:10

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-08-30T22:14:29', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '8ef1d7e5-3dc6-466b-b6e2-73aacf27a801'	System	31 Aug 2020 05:16:48
User entered 'Any use of prescription pain reliever or System prevents daily activity (3)'		31 Aug 2020 05:16:48

US3112389

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:14:10

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-08-30T22:14:51', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '8ef1d7e5-3dc6-466b-b6e2-73aacf27a801' User entered 'None (0)'	System	31 Aug 2020 05:16:48
	System	31 Aug 2020 05:16:48

US3112389

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:14:10

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-08-30T22:14:57', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '8ef1d7e5-3dc6-466b-b6e2-73aacf27a801' User entered 'None (0)'	System	31 Aug 2020 05:16:48
	System	31 Aug 2020 05:16:48

US3112389

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:14:10

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-08-30T22:15:05', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '8ef1d7e5-3dc6-466b-b6e2-73aacf27a801' User entered 'None (0)'	System	31 Aug 2020 05:16:48
	System	31 Aug 2020 05:16:48

US3112389

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:14:10

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-08-30T22:15:19', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '8ef1d7e5-3dc6-466b-b6e2-73aacf27a801'	System	31 Aug 2020 05:16:48
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	31 Aug 2020 05:16:48

US3112389

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:14:10

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-08-30T22:15:28', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '8ef1d7e5-3dc6-466b-b6e2-73aacf27a801' User entered 'None (0)'	System	31 Aug 2020 05:16:48
	System	31 Aug 2020 05:16:48

US3112389

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:14:10

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)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-08-30T22:15:52', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '8ef1d7e5-3dc6-466b-b6e2-73aacf27a801'	System	31 Aug 2020 05:16:48
User entered 'No (N)'	System	31 Aug 2020 05:16:48

US3112389

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:14:10

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-08-30T22:16:46', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '8ef1d7e5-3dc6-466b-b6e2-73aacf27a801' User entered '30 Aug 2020 22:16'	System	31 Aug 2020 05:16:48
	System	31 Aug 2020 05:16:48

US3112389

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:14:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
User entered '30 Aug 2020 12:00'	System	26 Aug 2020 23:03:15

US3112389

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:14:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
User entered '31 Aug 2020 11:59'	System	26 Aug 2020 23:03:15

US3112389

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
Data entry locked.	System	26 Aug 2020 23:03:15
User entered 'Day 6'	System	26 Aug 2020 23:03:15

US3112389

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:14:10

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-08-31T23:53:54', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: 'afaf4d22-155b-457e-898b-0cdbf0db4cef' User entered 'None (0)'	System	01 Sep 2020 06:54:33
	System	01 Sep 2020 06:54:33

US3112389

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:14:10

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-08-31T23:54:00', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: 'afaf4d22-155b-457e-898b-0cdbf0db4cef' User entered 'None (0)'	System	01 Sep 2020 06:54:33
	System	01 Sep 2020 06:54:33

US3112389

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:14:10

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-08-31T23:54:05', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: 'afaf4d22-155b-457e-898b-0cdbf0db4cef' User entered 'None (0)'	System	01 Sep 2020 06:54:33
	System	01 Sep 2020 06:54:33

US3112389

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:14:10

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-08-31T23:54:09', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: 'afaf4d22-155b-457e-898b-0cdbf0db4cef' User entered 'None (0)'	System	01 Sep 2020 06:54:33
	System	01 Sep 2020 06:54:33

US3112389

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:14:10

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-08-31T23:54:13', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: 'afaf4d22-155b-457e-898b-0cdbf0db4cef' User entered 'None (0)'	System	01 Sep 2020 06:54:33
	System	01 Sep 2020 06:54:33

US3112389

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:14:10

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-08-31T23:54:18', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: 'afaf4d22-155b-457e-898b-0cdbf0db4cef' User entered 'None (0)'	System	01 Sep 2020 06:54:33
	System	01 Sep 2020 06:54:33

US3112389

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:14:10

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)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-08-31T23:54:25', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: 'afaf4d22-155b-457e-898b-0cdbf0db4cef' User entered 'No (N)'	System	01 Sep 2020 06:54:33
	System	01 Sep 2020 06:54:33

US3112389

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:14:10

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-08-31T23:54:30', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: 'afaf4d22-155b-457e-898b-0cdbf0db4cef' User entered '31 Aug 2020 23:54'	System	01 Sep 2020 06:54:33
	System	01 Sep 2020 06:54:33

US3112389

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:14:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
User entered '31 Aug 2020 12:00'	System	26 Aug 2020 23:03:15

US3112389

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:14:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
User entered '01 Sep 2020 11:59'	System	26 Aug 2020 23:03:15

US3112389

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
Data entry locked.	System	26 Aug 2020 23:03:15
User entered 'Day 7'	System	26 Aug 2020 23:03:15

US3112389

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:14:10

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-09-01T21:03:31', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: 'eb2d94cc-66bc-448f-b5ba-e0a971309adf' User entered 'None (0)'	System	02 Sep 2020 04:04:15
	System	02 Sep 2020 04:04:15

US3112389

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:14:10

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-09-01T21:03:49', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: 'eb2d94cc-66bc-448f-b5ba-e0a971309adf' User entered 'None (0)'	System	02 Sep 2020 04:04:15
	System	02 Sep 2020 04:04:15

US3112389

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:14:10

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-09-01T21:03:52', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: 'eb2d94cc-66bc-448f-b5ba-e0a971309adf' User entered 'None (0)'	System	02 Sep 2020 04:04:15
	System	02 Sep 2020 04:04:15

US3112389

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:14:10

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-09-01T21:03:56', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: 'eb2d94cc-66bc-448f-b5ba-e0a971309adf' User entered 'None (0)'	System	02 Sep 2020 04:04:15
	System	02 Sep 2020 04:04:15

US3112389

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:14:10

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-09-01T21:03:59', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: 'eb2d94cc-66bc-448f-b5ba-e0a971309adf' User entered 'None (0)'	System	02 Sep 2020 04:04:15
	System	02 Sep 2020 04:04:15

US3112389

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:14:10

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-09-01T21:04:02', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: 'eb2d94cc-66bc-448f-b5ba-e0a971309adf' User entered 'None (0)'	System	02 Sep 2020 04:04:15
	System	02 Sep 2020 04:04:15

US3112389

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:14:10

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)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-09-01T21:04:06', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: 'eb2d94cc-66bc-448f-b5ba-e0a971309adf' User entered 'No (N)'	System	02 Sep 2020 04:04:15
	System	02 Sep 2020 04:04:15

US3112389

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:14:10

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-09-01T21:04:11', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: 'eb2d94cc-66bc-448f-b5ba-e0a971309adf' User entered '01 Sep 2020 21:04'	System	02 Sep 2020 04:04:15
	System	02 Sep 2020 04:04:15

US3112389

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:14:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
User entered '01 Sep 2020 12:00'	System	26 Aug 2020 23:03:15

US3112389

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:14:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
User entered '02 Sep 2020 11:59'	System	26 Aug 2020 23:03:15

US3112389

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:14:10

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 22:01:20
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	03 Sep 2020 00:51:30

US3112389

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:14:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 22:01:20
User entered '2 Sep 2020'	Karen Mylerberg (b) (4)	03 Sep 2020 00:51:30

US3112389

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:14:10

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 22:01:20
User entered 'Contact Made (CONTACT MADE)'	Karen Mylerberg (b) (4)	03 Sep 2020 00:51:30

US3112389

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:14:10

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 22:01:20
User entered empty.	Karen Mylerberg (b) (4)	03 Sep 2020 00:51:30

US3112389

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:14:10

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 22:01:20
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	03 Sep 2020 00:51:35

US3112389

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:14:10

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User entered 'I'	System	03 Sep 2020 00:51:35

US3112389

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:14:10

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 22:01:20
User entered 'No (N)'	Karen Mylerberg (b) (4)	17 Sep 2020 00:43:18

US3112389

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:14:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 22:01:20
User entered empty.	Karen Mylerberg (b) (4)	17 Sep 2020 00:43:18

US3112389

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:14:10

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 22:01:20
User entered empty.	Karen Mylerberg (b) (4)	17 Sep 2020 00:43:18

US3112389

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:14:10

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 22:01:20
User entered empty.	Karen Mylerberg (b) (4)	17 Sep 2020 00:43:18

US3112389

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:14:10

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 22:01:20
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	17 Sep 2020 00:43:23

US3112389

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:14:10

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User entered 'I'	System	17 Sep 2020 00:43:23

US3112389

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:14:10

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 22:01:20
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	17 Sep 2020 00:43:33

US3112389

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:14:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 22:01:20
User entered '16 Sep 2020'	Karen Mylerberg (b) (4)	17 Sep 2020 00:43:33

US3112389

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:14:10

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 22:01:20
User entered 'Contact Made (CONTACT MADE)'	Karen Mylerberg (b) (4)	17 Sep 2020 00:43:33

US3112389

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:14:10

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 22:01:20
User entered empty.	Karen Mylerberg (b) (4)	17 Sep 2020 00:43:33

US3112389

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:14:10

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 22:01:20
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	17 Sep 2020 00:43:39

US3112389

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:14:10

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User entered 'I'	System	17 Sep 2020 00:43:39

US3112389

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:14:10

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 22:01:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 22:30:34

US3112389

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:14:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 22:01:20
User entered '23 Sep 2020'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 22:30:34

US3112389

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:14:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 22:01:20
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 22:30:34

US3112389

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:14:10

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User entered 'VISIT2'	System	23 Sep 2020 22:30:34

US3112389

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:14:10

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User accepted default value 'Pre-Dose (PREDOSE)'	Karen Mylerberg (b) (4)	24 Sep 2020 14:27:00
	(b) (4)	

US3112389

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:14:10

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 22:01:20
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	24 Sep 2020 14:27:00

US3112389

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:14:10

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 22:01:20
User entered '23 Sep 2020'	Karen Mylerberg (b) (4)	24 Sep 2020 14:27:00

US3112389

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:14:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 22:01:20
User entered '14:39'	Karen Mylerberg (b) (4)	24 Sep 2020 14:27:00

US3112389

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:14:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User entered '23 Sep 2020 14:39'	System	24 Sep 2020 14:27:00

US3112389

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:14:10

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 22:01:20
User entered '98.8' F	Karen Mylerberg (b) (4)	24 Sep 2020 14:27:00

US3112389

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:14:10

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 22:01:20
User entered 'Oral (Oral)'	Karen Mylerberg (b) (4)	24 Sep 2020 14:27:00

US3112389

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:14:10

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 22:01:20
User entered empty.	Karen Mylerberg (b) (4)	24 Sep 2020 14:27:00

US3112389

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:14:10

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 22:01:20
User entered '70'	Karen Mylerberg (b) (4)	24 Sep 2020 14:27:00

US3112389

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:14:10

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User entered 'bpm'	System	24 Sep 2020 14:27:00

US3112389

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:14:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 22:01:20
User entered '16'	Karen Mylerberg (b) (4)	24 Sep 2020 14:27:00

US3112389

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:14:10

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User entered 'breaths/min'	System	24 Sep 2020 14:27:00

US3112389

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:14:10

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 22:01:20
User entered '119'	Karen Mylerberg (b) (4)	24 Sep 2020 14:27:00

US3112389

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:14:10

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User entered 'mmHg'	System	24 Sep 2020 14:27:00

US3112389

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:14:10

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 22:01:20
User entered '078'	Karen Mylerberg (b) (4)	24 Sep 2020 14:27:00

US3112389

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:14:10

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User entered 'mmHg'	System	24 Sep 2020 14:27:00

US3112389

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:14:10

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User accepted default value 'Post-Dose (POSTDOSE)'	Karen Mylerberg (b) (4)	24 Sep 2020 14:27:00

US3112389

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:14:10

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 22:01:20
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	24 Sep 2020 14:27:00

US3112389

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:14:10

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 22:01:20
User entered '23 Sep 2020'	Karen Mylerberg (b) (4)	24 Sep 2020 14:27:00

US3112389

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:14:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 22:01:20
User entered '15:59'	Karen Mylerberg (b) (4)	24 Sep 2020 14:27:00

US3112389

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:14:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User entered '23 Sep 2020 15:59'	System	24 Sep 2020 14:27:00

US3112389

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:14:10

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 22:01:20
User entered '97.9' F	Karen Mylerberg (b) (4)	24 Sep 2020 14:27:00

US3112389

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:14:10

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 22:01:20
User entered 'Oral (Oral)'	Karen Mylerberg (b) (4)	24 Sep 2020 14:27:00

US3112389

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:14:10

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 22:01:20
User entered empty.	Karen Mylerberg (b) (4)	24 Sep 2020 14:27:00

US3112389

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:14:10

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 22:01:20
User entered '66'	Karen Mylerberg (b) (4)	24 Sep 2020 14:27:00

US3112389

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:14:10

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User entered 'bpm'	System	24 Sep 2020 14:27:00

US3112389

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:14:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 22:01:20
User entered '16'	Karen Mylerberg (b) (4)	24 Sep 2020 14:27:00

US3112389

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:14:10

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User entered 'breaths/min'	System	24 Sep 2020 14:27:00

US3112389

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:14:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 22:01:20
User entered '100'	Karen Mylerberg (b) (4)	24 Sep 2020 14:27:00

US3112389

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:14:10

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User entered 'mmHg'	System	24 Sep 2020 14:27:00

US3112389

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:14:10

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 22:01:20
User entered '068'	Karen Mylerberg (b) (4)	24 Sep 2020 14:27:00

US3112389

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:14:10

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User entered 'mmHg'	System	24 Sep 2020 14:27:00

US3112389

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:14:10

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 22:01:20
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	Karen Mylerberg (b) (4)	19 Oct 2020 19:44:12
User entered 'No (N)'	(b) (4)	
	Karen Mylerberg (b) (4)	24 Sep 2020 14:27:09
	(b) (4)	

US3112389

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:14:10

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 22:01:20
User entered '23 Sep 2020' reason for change: Data Entry Error	(b) (4)	
	Karen Mylerberg (b) (4)	19 Oct 2020 19:44:12
User entered empty.	(b) (4)	
	Karen Mylerberg (b) (4)	24 Sep 2020 14:27:09
	(b) (4)	

US3112389

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:14:10

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 22:01:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 22:30:48

US3112389

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:14:10

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 22:01:20
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 22:30:48

US3112389

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:14:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 22:01:20
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 22:30:48

US3112389

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:14:10

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User entered 'MRNA-1273 OR PLACEBO'	System	23 Sep 2020 22:30:48

US3112389

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:14:10

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 22:01:20
User entered '23 Sep 2020'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 22:30:48

US3112389

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:14:10

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 22:01:20
User entered '15:25'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 22:30:48

US3112389

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:14:10

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User entered '23 Sep 2020 15:25'	System	23 Sep 2020 22:30:48

US3112389

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:14:10

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 22:01:20
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 22:30:48

US3112389

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:14:10

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User entered 'ONCE'	System	23 Sep 2020 22:30:48

US3112389

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:14:10

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User entered 'INTRAMUSCULAR'	System	23 Sep 2020 22:30:48

US3112389

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:14:10

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 22:01:20
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	24 Sep 2020 14:27:27

US3112389

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:14:10

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 22:01:20
User entered '23 Sep 2020'	Karen Mylerberg (b) (4)	24 Sep 2020 14:27:27

US3112389

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:14:10

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 22:01:20
User entered '15:04'	Karen Mylerberg (b) (4)	24 Sep 2020 14:27:27

US3112389

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:14:10

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User entered '23 Sep 2020 15:04'	System	24 Sep 2020 14:27:27

US3112389

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:14:10

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 22:01:20
User entered '23 Sep 2020'	Karen Mylerberg (b) (4)	24 Sep 2020 14:27:44

US3112389

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:14:10

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Karen Mylerberg (b) (4)	24 Sep 2020 14:27:44

US3112389

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:14:10

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 22:01:20
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	24 Sep 2020 14:27:44

US3112389

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:14:10

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 22:01:20
User entered '14:56'	Karen Mylerberg (b) (4)	24 Sep 2020 14:27:44

US3112389

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:14:10

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User entered '23 Sep 2020 14:56'	System	24 Sep 2020 14:27:44

US3112389

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:14:10

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Karen Mylerberg (b) (4)	24 Sep 2020 14:27:44

US3112389

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:14:10

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 22:01:20
User entered 'No (N)'	Karen Mylerberg (b) (4)	24 Sep 2020 14:27:44

US3112389

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:14:10

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 22:01:20
User entered empty.	Karen Mylerberg (b) (4)	24 Sep 2020 14:27:44

US3112389

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:14:10

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User entered empty.	System	24 Sep 2020 14:27:44

US3112389

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:14:10

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 22:01:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 22:30:53

US3112389

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:14:10

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User entered 'I'	System	23 Sep 2020 22:30:53

US3112389

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
Data entry locked.	System	23 Sep 2020 22:30:48
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	23 Sep 2020 22:30:48

US3112389

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:14:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-09-23T15:55:43', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '52227e35-7b36-4ed1-a45a-a8195af9f7a6' User entered 'Yes (Y)'	System	23 Sep 2020 22:56:15
	System	23 Sep 2020 22:56:15

US3112389

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:14:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-09-23T15:55:53', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '52227e35-7b36-4ed1-a45a-a8195af9f7a6' User entered '97.9'	System	23 Sep 2020 22:56:15
	System	23 Sep 2020 22:56:15

US3112389

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:14:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-09-23T15:55:58', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '52227e35-7b36-4ed1-a45a-a8195af9f7a6'	System	23 Sep 2020 22:56:15
User entered 'No (N)'	System	23 Sep 2020 22:56:15

US3112389

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:14:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-09-23T15:56:04', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '52227e35-7b36-4ed1-a45a-a8195af9f7a6'	System	23 Sep 2020 22:56:15
User entered '23 Sep 2020 15:56'	System	23 Sep 2020 22:56:15

US3112389

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:14:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
User entered '23 Sep 2020 15:45'	System	23 Sep 2020 22:30:48

US3112389

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:14:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
User entered '23 Sep 2020 18:15'	System	23 Sep 2020 22:30:48

US3112389

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
Data entry locked.	System	23 Sep 2020 22:30:48
User entered 'Day 1, after vaccination (at home)'	System	23 Sep 2020 22:30:48

US3112389

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:14:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-09-23T22:10:03', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '7452afcb-38c6-4346-b449-d3b1d4733403' User entered 'Yes (Y)'	System	24 Sep 2020 05:10:24
	System	24 Sep 2020 05:10:24

US3112389

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:14:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-09-23T22:10:08', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '7452afcb-38c6-4346-b449-d3b1d4733403' User entered '97.8'	System	24 Sep 2020 05:10:24
	System	24 Sep 2020 05:10:24

US3112389

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:14:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-09-23T22:10:12', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '7452afcb-38c6-4346-b449-d3b1d4733403' User entered 'No (N)'	System	24 Sep 2020 05:10:24
	System	24 Sep 2020 05:10:24

US3112389

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:14:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-09-23T22:10:22', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '7452afcb-38c6-4346-b449-d3b1d4733403' User entered '23 Sep 2020 22:10'	System	24 Sep 2020 05:10:24
	System	24 Sep 2020 05:10:24

US3112389

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:14:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
User entered '23 Sep 2020 19:10'	System	23 Sep 2020 22:30:48

US3112389

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:14:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
User entered '24 Sep 2020 11:59'	System	23 Sep 2020 22:30:48

US3112389

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
Data entry locked.	System	23 Sep 2020 22:30:48
User entered 'Day 2'	System	23 Sep 2020 22:30:48

US3112389

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:14:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-09-25T09:26:33', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '51dc30c3-0045-45ac-819d-6380b12add55' User entered 'Yes (Y)'	System	25 Sep 2020 16:26:52
	System	25 Sep 2020 16:26:52

US3112389

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:14:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-09-25T09:26:39', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '51dc30c3-0045-45ac-819d-6380b12add55' User entered '97.4'	System	25 Sep 2020 16:26:52
	System	25 Sep 2020 16:26:52

US3112389

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:14:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-09-25T09:26:45', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '51dc30c3-0045-45ac-819d-6380b12add55'	System	25 Sep 2020 16:26:52
User entered 'No (N)'	System	25 Sep 2020 16:26:52

US3112389

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:14:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-09-25T09:26:50', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '51dc30c3-0045-45ac-819d-6380b12add55' User entered '25 Sep 2020 09:26'	System	25 Sep 2020 16:26:52
	System	25 Sep 2020 16:26:52

US3112389

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:14:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
User entered '24 Sep 2020 12:00'	System	23 Sep 2020 22:30:48

US3112389

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:14:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
User entered '25 Sep 2020 11:59'	System	23 Sep 2020 22:30:48

US3112389

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
Data entry locked.	System	23 Sep 2020 22:30:48
User entered 'Day 3'	System	23 Sep 2020 22:30:48

US3112389

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:14:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-09-25T12:35:11', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '75b84196-1e21-440f-aa84-b2c6fdd91b76' User entered 'Yes (Y)'	System	25 Sep 2020 19:35:38
	System	25 Sep 2020 19:35:38

US3112389

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:14:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-09-25T12:35:17', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '75b84196-1e21-440f-aa84-b2c6fdd91b76' User entered '98.5'	System	25 Sep 2020 19:35:38
	System	25 Sep 2020 19:35:38

US3112389

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:14:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-09-25T12:35:26', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '75b84196-1e21-440f-aa84-b2c6fdd91b76'	System	25 Sep 2020 19:35:38
User entered 'No (N)'	System	25 Sep 2020 19:35:38

US3112389

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:14:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-09-25T12:35:31', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '75b84196-1e21-440f-aa84-b2c6fdd91b76' User entered '25 Sep 2020 12:35'	System	25 Sep 2020 19:35:38
	System	25 Sep 2020 19:35:38

US3112389

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:14:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
User entered '25 Sep 2020 12:00'	System	23 Sep 2020 22:30:48

US3112389

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:14:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
User entered '26 Sep 2020 11:59'	System	23 Sep 2020 22:30:48

US3112389

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
Data entry locked.	System	23 Sep 2020 22:30:48
User entered 'Day 4'	System	23 Sep 2020 22:30:48

US3112389

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:14:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-09-26T12:50:01', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: 'c5b6f90b-2d60-4aaf-8a18-79310057c141' User entered 'Yes (Y)'	System	26 Sep 2020 19:50:19
	System	26 Sep 2020 19:50:19

US3112389

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:14:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-09-26T12:50:06', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: 'c5b6f90b-2d60-4aaf-8a18-79310057c141' User entered '97.7'	System	26 Sep 2020 19:50:19
	System	26 Sep 2020 19:50:19

US3112389

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:14:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-09-26T12:50:12', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: 'c5b6f90b-2d60-4aaf-8a18-79310057c141' User entered 'No (N)'	System	26 Sep 2020 19:50:19
	System	26 Sep 2020 19:50:19

US3112389

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:14:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-09-26T12:50:17', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: 'c5b6f90b-2d60-4aaf-8a18-79310057c141' User entered '26 Sep 2020 12:50'	System	26 Sep 2020 19:50:19
	System	26 Sep 2020 19:50:19

US3112389

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:14:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
User entered '26 Sep 2020 12:00'	System	23 Sep 2020 22:30:48

US3112389

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:14:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
User entered '27 Sep 2020 11:59'	System	23 Sep 2020 22:30:48

US3112389

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
Data entry locked.	System	23 Sep 2020 22:30:48
User entered 'Day 5'	System	23 Sep 2020 22:30:48

US3112389

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:14:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-09-27T22:39:28', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '9c7e51bb-9efb-48c5-8697-b309fb441b9d' User entered 'Yes (Y)'	System	28 Sep 2020 05:39:48
	System	28 Sep 2020 05:39:48

US3112389

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:14:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-09-27T22:39:34', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '9c7e51bb-9efb-48c5-8697-b309fb441b9d' User entered '97.3'	System	28 Sep 2020 05:39:48
	System	28 Sep 2020 05:39:48

US3112389

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:14:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-09-27T22:39:40', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '9c7e51bb-9efb-48c5-8697-b309fb441b9d' User entered 'No (N)'	System	28 Sep 2020 05:39:48
	System	28 Sep 2020 05:39:48

US3112389

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:14:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-09-27T22:39:44', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '9c7e51bb-9efb-48c5-8697-b309fb441b9d' User entered '27 Sep 2020 22:39'	System	28 Sep 2020 05:39:48
	System	28 Sep 2020 05:39:48

US3112389

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:14:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
User entered '27 Sep 2020 12:00'	System	23 Sep 2020 22:30:48

US3112389

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:14:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
User entered '28 Sep 2020 11:59'	System	23 Sep 2020 22:30:48

US3112389

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
Data entry locked.	System	23 Sep 2020 22:30:48
User entered 'Day 6'	System	23 Sep 2020 22:30:48

US3112389

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:14:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-09-29T09:07:36', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '6eae408-3d48-49d8-bc12-1c1bfd5a72ad' User entered 'Yes (Y)'	System	29 Sep 2020 16:07:51
	System	29 Sep 2020 16:07:51

US3112389

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:14:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-09-29T09:07:40', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '6eae408-3d48-49d8-bc12-1c1bfd5a72ad' User entered '97.9'	System	29 Sep 2020 16:07:51
	System	29 Sep 2020 16:07:51

US3112389

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:14:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-09-29T09:07:44', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '6eae408-3d48-49d8-bc12-1c1bfd5a72ad' User entered 'No (N)'	System	29 Sep 2020 16:07:51
	System	29 Sep 2020 16:07:51

US3112389

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:14:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-09-29T09:07:48', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '6eae408-3d48-49d8-bc12-1c1bfd5a72ad' User entered '29 Sep 2020 09:07'	System	29 Sep 2020 16:07:51
	System	29 Sep 2020 16:07:51

US3112389

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:14:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
User entered '28 Sep 2020 12:00'	System	23 Sep 2020 22:30:48

US3112389

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:14:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
User entered '29 Sep 2020 11:59'	System	23 Sep 2020 22:30:48

US3112389

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
Data entry locked.	System	23 Sep 2020 22:30:48
User entered 'Day 7'	System	23 Sep 2020 22:30:48

US3112389

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:14:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-09-30T06:53:10', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: 'c51d337a-42aa-4db1-b5a4-adaa5621d14f' User entered 'Yes (Y)'	System	30 Sep 2020 13:53:27
	System	30 Sep 2020 13:53:27

US3112389

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:14:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-09-30T06:53:15', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: 'c51d337a-42aa-4db1-b5a4-adaa5621d14f' User entered '97.1'	System	30 Sep 2020 13:53:27
	System	30 Sep 2020 13:53:27

US3112389

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:14:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-09-30T06:53:18', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: 'c51d337a-42aa-4db1-b5a4-adaa5621d14f' User entered 'No (N)'	System	30 Sep 2020 13:53:27
	System	30 Sep 2020 13:53:27

US3112389

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:14:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-09-30T06:53:25', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: 'c51d337a-42aa-4db1-b5a4-adaa5621d14f' User entered '30 Sep 2020 06:53'	System	30 Sep 2020 13:53:27
	System	30 Sep 2020 13:53:27

US3112389

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:14:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
User entered '29 Sep 2020 12:00'	System	23 Sep 2020 22:30:48

US3112389

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:14:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
User entered '30 Sep 2020 11:59'	System	23 Sep 2020 22:30:48

US3112389

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
Data entry locked.	System	23 Sep 2020 22:30:48
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	23 Sep 2020 22:30:48

US3112389

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:14:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-09-23T15:56:18', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '90a98f00-b2d8-4b2a-b209-eaffaef266f5'	System	23 Sep 2020 22:56:55
User entered 'None (1)'	System	23 Sep 2020 22:56:55

US3112389

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:14:10

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-09-23T15:56:25', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '90a98f00-b2d8-4b2a-b209-eaffaef266f5' User entered 'No (N)'	System	23 Sep 2020 22:56:55
	System	23 Sep 2020 22:56:55

US3112389

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:14:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-09-23T15:56:39', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '90a98f00-b2d8-4b2a-b209-eaffaef266f5' User entered 'No (N)'	System	23 Sep 2020 22:56:55
	System	23 Sep 2020 22:56:55

US3112389

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:14:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-09-23T15:56:46', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '90a98f00-b2d8-4b2a-b209-eaffaef266f5'	System	23 Sep 2020 22:56:55
User entered 'None (1)'	System	23 Sep 2020 22:56:55

US3112389

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:14:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-09-23T15:56:53', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '90a98f00-b2d8-4b2a-b209-eaffaef266f5' User entered '23 Sep 2020 15:56'	System	23 Sep 2020 22:56:55
	System	23 Sep 2020 22:56:55

US3112389

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:14:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
User entered '23 Sep 2020 15:45'	System	23 Sep 2020 22:30:48

US3112389

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:14:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
User entered '23 Sep 2020 18:15'	System	23 Sep 2020 22:30:48

US3112389

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
Data entry locked.	System	23 Sep 2020 22:30:48
User entered 'Day 1, after vaccination (at home)'	System	23 Sep 2020 22:30:48

US3112389

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:14:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-09-23T22:10:30', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: 'c6162dd9-cf36-46fb-9cf9-9caebb5dad75'	System	24 Sep 2020 05:10:51
User entered 'None (1)'	System	24 Sep 2020 05:10:51

US3112389

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:14:10

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-09-23T22:10:33', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: 'c6162dd9-cf36-46fb-9cf9-9caebb5dad75' User entered 'No (N)'	System	24 Sep 2020 05:10:51
	System	24 Sep 2020 05:10:51

US3112389

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:14:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-09-23T22:10:37', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: 'c6162dd9-cf36-46fb-9cf9-9caebb5dad75' User entered 'No (N)'	System	24 Sep 2020 05:10:51
	System	24 Sep 2020 05:10:51

US3112389

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:14:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-09-23T22:10:44', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: 'c6162dd9-cf36-46fb-9cf9-9cae5bb5dad75'	System	24 Sep 2020 05:10:51
User entered 'None (1)'	System	24 Sep 2020 05:10:51

US3112389

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:14:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-09-23T22:10:48', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: 'c6162dd9-cf36-46fb-9cf9-9caebb5dad75' User entered '23 Sep 2020 22:10'	System	24 Sep 2020 05:10:51
	System	24 Sep 2020 05:10:51

US3112389

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:14:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
User entered '23 Sep 2020 19:10'	System	23 Sep 2020 22:30:48

US3112389

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:14:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
User entered '24 Sep 2020 11:59'	System	23 Sep 2020 22:30:48

US3112389

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
Data entry locked.	System	23 Sep 2020 22:30:48
User entered 'Day 2'	System	23 Sep 2020 22:30:48

US3112389

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:14:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-09-25T09:24:02', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '4a75da4d-a0a7-462c-95d0-0e4f4220f4a6'	System	25 Sep 2020 16:25:37
User entered 'Does not interfere with activity (2)'	System	25 Sep 2020 16:25:37

US3112389

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:14:10

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-09-25T09:24:07', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '4a75da4d-a0a7-462c-95d0-0e4f4220f4a6' User entered 'No (N)'	System	25 Sep 2020 16:25:37
	System	25 Sep 2020 16:25:37

US3112389

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:14:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-09-25T09:25:03', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '4a75da4d-a0a7-462c-95d0-0e4f4220f4a6' User entered 'No (N)'	System	25 Sep 2020 16:25:37
	System	25 Sep 2020 16:25:37

US3112389

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:14:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-09-25T09:25:12', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '4a75da4d-a0a7-462c-95d0-0e4f4220f4a6' User entered 'None (1)'	System	25 Sep 2020 16:25:37
	System	25 Sep 2020 16:25:37

US3112389

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:14:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-09-25T09:25:29', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '4a75da4d-a0a7-462c-95d0-0e4f4220f4a6' User entered '25 Sep 2020 09:25'	System	25 Sep 2020 16:25:37
	System	25 Sep 2020 16:25:37

US3112389

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:14:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
User entered '24 Sep 2020 12:00'	System	23 Sep 2020 22:30:48

US3112389

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:14:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
User entered '25 Sep 2020 11:59'	System	23 Sep 2020 22:30:48

US3112389

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
Data entry locked.	System	23 Sep 2020 22:30:48
User entered 'Day 3'	System	23 Sep 2020 22:30:48

US3112389

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:14:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-09-25T12:35:43', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '975c811f-647d-4a61-950b-b8b303a23976'	System	25 Sep 2020 19:38:33
User entered 'Does not interfere with activity (2)'	System	25 Sep 2020 19:38:33

US3112389

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:14:10

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-09-25T12:35:56', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '975c811f-647d-4a61-950b-b8b303a23976' User entered 'No (N)'	System	25 Sep 2020 19:38:33
	System	25 Sep 2020 19:38:33

US3112389

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:14:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-09-25T12:36:02', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '975c811f-647d-4a61-950b-b8b303a23976' User entered 'Yes (Y)'	System	25 Sep 2020 19:38:33
	System	25 Sep 2020 19:38:33

US3112389

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:14:10

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-09-25T12:38:19', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '975c811f-647d-4a61-950b-b8b303a23976' User entered '10'	System	25 Sep 2020 19:38:33
	System	25 Sep 2020 19:38:33

US3112389

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:14:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-09-25T12:38:26', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '975c811f-647d-4a61-950b-b8b303a23976' User entered 'None (1)'	System	25 Sep 2020 19:38:33
	System	25 Sep 2020 19:38:33

US3112389

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:14:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-09-25T12:38:30', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '975c811f-647d-4a61-950b-b8b303a23976' User entered '25 Sep 2020 12:38'	System	25 Sep 2020 19:38:33
	System	25 Sep 2020 19:38:33

US3112389

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:14:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
User entered '25 Sep 2020 12:00'	System	23 Sep 2020 22:30:48

US3112389

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:14:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
User entered '26 Sep 2020 11:59'	System	23 Sep 2020 22:30:48

US3112389

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
Data entry locked.	System	23 Sep 2020 22:30:48
User entered 'Day 4'	System	23 Sep 2020 22:30:48

US3112389

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:14:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-09-26T12:50:33', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: 'bc33848a-626b-451f-baef-26c6d907b319'	System	26 Sep 2020 19:53:47
User entered 'Does not interfere with activity (2)'	System	26 Sep 2020 19:53:47

US3112389

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:14:10

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-09-26T12:50:41', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: 'bc33848a-626b-451f-baef-26c6d907b319' User entered 'Yes (Y)'	System	26 Sep 2020 19:53:47
	System	26 Sep 2020 19:53:47

US3112389

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:14:10

Please record - **REDNESS AT INJECTION SITE (in mm)**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-09-26T12:52:12', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: 'bc33848a-626b-451f-baef-26c6d907b319' User entered '9'	System	26 Sep 2020 19:53:47
	System	26 Sep 2020 19:53:47

US3112389

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:14:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-09-26T12:52:18', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: 'bc33848a-626b-451f-baef-26c6d907b319' User entered 'Yes (Y)'	System	26 Sep 2020 19:53:47
	System	26 Sep 2020 19:53:47

US3112389

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:14:10

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-09-26T12:53:24', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: 'bc33848a-626b-451f-baef-26c6d907b319' User entered '1'	System	26 Sep 2020 19:53:47
	System	26 Sep 2020 19:53:47

US3112389

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:14:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-09-26T12:53:30', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: 'bc33848a-626b-451f-baef-26c6d907b319' User entered 'None (1)'	System	26 Sep 2020 19:53:47
	System	26 Sep 2020 19:53:47

US3112389

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:14:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-09-26T12:53:45', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: 'bc33848a-626b-451f-baef-26c6d907b319' User entered '26 Sep 2020 12:53'	System	26 Sep 2020 19:53:47
	System	26 Sep 2020 19:53:47

US3112389

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:14:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
User entered '26 Sep 2020 12:00'	System	23 Sep 2020 22:30:48

US3112389

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:14:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
User entered '27 Sep 2020 11:59'	System	23 Sep 2020 22:30:48

US3112389

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
Data entry locked.	System	23 Sep 2020 22:30:48
User entered 'Day 5'	System	23 Sep 2020 22:30:48

US3112389

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:14:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-09-27T22:39:57', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '470ab063-c737-4c85-9fc1-c2aac66adcf0' User entered 'Does not interfere with activity (2)'	System	28 Sep 2020 05:42:49
	System	28 Sep 2020 05:42:49

US3112389

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:14:10

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-09-27T22:40:11', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '470ab063-c737-4c85-9fc1-c2aac66adcf0' User entered 'Yes (Y)'	System	28 Sep 2020 05:42:49
	System	28 Sep 2020 05:42:49

US3112389

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:14:10

Please record - **REDNESS AT INJECTION SITE (in mm)**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-09-27T22:41:54', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '470ab063-c737-4c85-9fc1-c2aac66adcf0' User entered '9'	System	28 Sep 2020 05:42:49
	System	28 Sep 2020 05:42:49

US3112389

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:14:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-09-27T22:42:04', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '470ab063-c737-4c85-9fc1-c2aac66adcf0' User entered 'No (N)'	System	28 Sep 2020 05:42:49
	System	28 Sep 2020 05:42:49

US3112389

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:14:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-09-27T22:42:41', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '470ab063-c737-4c85-9fc1-c2aac66adcf0' User entered 'None (1)'	System	28 Sep 2020 05:42:49
	System	28 Sep 2020 05:42:49

US3112389

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:14:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-09-27T22:42:48', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '470ab063-c737-4c85-9fc1-c2aac66adcf0' User entered '27 Sep 2020 22:42'	System	28 Sep 2020 05:42:49
	System	28 Sep 2020 05:42:49

US3112389

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:14:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
User entered '27 Sep 2020 12:00'	System	23 Sep 2020 22:30:48

US3112389

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:14:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
User entered '28 Sep 2020 11:59'	System	23 Sep 2020 22:30:48

US3112389

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
Data entry locked.	System	23 Sep 2020 22:30:48
User entered 'Day 6'	System	23 Sep 2020 22:30:48

US3112389

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:14:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-09-29T09:07:57', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '90e75bda-8660-4680-9797-7ef121c4a43b' User entered 'None (1)'	System	29 Sep 2020 16:08:38
	System	29 Sep 2020 16:08:38

US3112389

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:14:10

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-09-29T09:08:00', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '90e75bda-8660-4680-9797-7ef121c4a43b' User entered 'No (N)'	System	29 Sep 2020 16:08:38
	System	29 Sep 2020 16:08:38

US3112389

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:14:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-09-29T09:08:02', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '90e75bda-8660-4680-9797-7ef121c4a43b' User entered 'No (N)'	System	29 Sep 2020 16:08:38
	System	29 Sep 2020 16:08:38

US3112389

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:14:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-09-29T09:08:08', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '90e75bda-8660-4680-9797-7ef121c4a43b' User entered 'None (1)'	System	29 Sep 2020 16:08:38
	System	29 Sep 2020 16:08:38

US3112389

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:14:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-09-29T09:08:14', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '90e75bda-8660-4680-9797-7ef121c4a43b' User entered '29 Sep 2020 09:08'	System	29 Sep 2020 16:08:38
	System	29 Sep 2020 16:08:38

US3112389

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:14:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
User entered '28 Sep 2020 12:00'	System	23 Sep 2020 22:30:48

US3112389

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:14:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
User entered '29 Sep 2020 11:59'	System	23 Sep 2020 22:30:48

US3112389

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
Data entry locked.	System	23 Sep 2020 22:30:48
User entered 'Day 7'	System	23 Sep 2020 22:30:48

US3112389

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:14:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-09-30T06:53:30', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: 'e6664993-d96e-4626-ae3e-78737f395573' User entered 'None (1)'	System	30 Sep 2020 13:53:49
	System	30 Sep 2020 13:53:49

US3112389

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:14:10

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-09-30T06:53:34', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: 'e6664993-d96e-4626-ae3e-78737f395573'	System	30 Sep 2020 13:53:49
User entered 'No (N)'	System	30 Sep 2020 13:53:49

US3112389

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:14:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-09-30T06:53:37', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: 'e6664993-d96e-4626-ae3e-78737f395573' User entered 'No (N)'	System	30 Sep 2020 13:53:49
	System	30 Sep 2020 13:53:49

US3112389

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:14:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-09-30T06:53:40', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: 'e6664993-d96e-4626-ae3e-78737f395573' User entered 'None (1)'	System	30 Sep 2020 13:53:49
	System	30 Sep 2020 13:53:49

US3112389

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:14:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-09-30T06:53:46', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: 'e6664993-d96e-4626-ae3e-78737f395573' User entered '30 Sep 2020 06:53'	System	30 Sep 2020 13:53:49
	System	30 Sep 2020 13:53:49

US3112389

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:14:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
User entered '29 Sep 2020 12:00'	System	23 Sep 2020 22:30:48

US3112389

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:14:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
User entered '30 Sep 2020 11:59'	System	23 Sep 2020 22:30:48

US3112389

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
Data entry locked.	System	23 Sep 2020 22:30:48
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	23 Sep 2020 22:30:48

US3112389

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:14:10

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-09-23T15:56:59', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: 'a08159f2-c9af-4321-84f6-21f34a501cdc' User entered 'None (0)'	System	23 Sep 2020 22:57:46
	System	23 Sep 2020 22:57:46

US3112389

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:14:10

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-09-23T15:57:04', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: 'a08159f2-c9af-4321-84f6-21f34a501cdc' User entered 'None (0)'	System	23 Sep 2020 22:57:46
	System	23 Sep 2020 22:57:46

US3112389

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:14:10

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-09-23T15:57:13', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: 'a08159f2-c9af-4321-84f6-21f34a501cdc' User entered 'None (0)'	System	23 Sep 2020 22:57:46
	System	23 Sep 2020 22:57:46

US3112389

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:14:10

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-09-23T15:57:16', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: 'a08159f2-c9af-4321-84f6-21f34a501cdc' User entered 'None (0)'	System	23 Sep 2020 22:57:46
	System	23 Sep 2020 22:57:46

US3112389

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:14:10

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-09-23T15:57:21', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: 'a08159f2-c9af-4321-84f6-21f34a501cdc' User entered 'None (0)'	System	23 Sep 2020 22:57:46
	System	23 Sep 2020 22:57:46

US3112389

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:14:10

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-09-23T15:57:31', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: 'a08159f2-c9af-4321-84f6-21f34a501cdc' User entered 'None (0)'	System	23 Sep 2020 22:57:46
	System	23 Sep 2020 22:57:46

US3112389

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:14:10

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)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-09-23T15:57:40', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: 'a08159f2-c9af-4321-84f6-21f34a501cdc' User entered 'No (N)'	System	23 Sep 2020 22:57:46
	System	23 Sep 2020 22:57:46

US3112389

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:14:10

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-09-23T15:57:44', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: 'a08159f2-c9af-4321-84f6-21f34a501cdc' User entered '23 Sep 2020 15:57'	System	23 Sep 2020 22:57:46
	System	23 Sep 2020 22:57:46

US3112389

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:14:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
User entered '23 Sep 2020 15:45'	System	23 Sep 2020 22:30:48

US3112389

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:14:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
User entered '23 Sep 2020 18:15'	System	23 Sep 2020 22:30:48

US3112389

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
Data entry locked.	System	23 Sep 2020 22:30:48
User entered 'Day 1, after vaccination (at home)'	System	23 Sep 2020 22:30:48

US3112389

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:14:10

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-09-23T22:10:56', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: 'f0d813af-ef0d-4144-9de1-8960eb1130e2' User entered 'None (0)'	System	24 Sep 2020 05:11:32
	System	24 Sep 2020 05:11:32

US3112389

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:14:10

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-09-23T22:11:07', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: 'f0d813af-ef0d-4144-9de1-8960eb1130e2' User entered 'None (0)'	System	24 Sep 2020 05:11:32
	System	24 Sep 2020 05:11:32

US3112389

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:14:10

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-09-23T22:11:10', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: 'f0d813af-ef0d-4144-9de1-8960eb1130e2' User entered 'None (0)'	System	24 Sep 2020 05:11:32
	System	24 Sep 2020 05:11:32

US3112389

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:14:10

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-09-23T22:11:12', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: 'f0d813af-ef0d-4144-9de1-8960eb1130e2' User entered 'None (0)'	System	24 Sep 2020 05:11:32
	System	24 Sep 2020 05:11:32

US3112389

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:14:10

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-09-23T22:11:15', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: 'f0d813af-ef0d-4144-9de1-8960eb1130e2' User entered 'None (0)'	System	24 Sep 2020 05:11:32
	System	24 Sep 2020 05:11:32

US3112389

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:14:10

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-09-23T22:11:18', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: 'f0d813af-ef0d-4144-9de1-8960eb1130e2' User entered 'None (0)'	System	24 Sep 2020 05:11:32
	System	24 Sep 2020 05:11:32

US3112389

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:14:10

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)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-09-23T22:11:23', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: 'f0d813af-ef0d-4144-9de1-8960eb1130e2'	System	24 Sep 2020 05:11:32
User entered 'No (N)'	System	24 Sep 2020 05:11:32

US3112389

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:14:10

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-09-23T22:11:29', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: 'f0d813af-ef0d-4144-9de1-8960eb1130e2' User entered '23 Sep 2020 22:11'	System	24 Sep 2020 05:11:32
	System	24 Sep 2020 05:11:32

US3112389

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:14:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
User entered '23 Sep 2020 19:10'	System	23 Sep 2020 22:30:48

US3112389

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:14:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
User entered '24 Sep 2020 11:59'	System	23 Sep 2020 22:30:48

US3112389

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
Data entry locked.	System	23 Sep 2020 22:30:48
User entered 'Day 2'	System	23 Sep 2020 22:30:48

US3112389

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:14:10

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-09-25T09:28:14', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: 'eb7c64df-5357-4685-9658-682bbf276058' User entered 'None (0)'	System	25 Sep 2020 16:29:11
	System	25 Sep 2020 16:29:11

US3112389

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:14:10

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-09-25T09:28:25', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: 'eb7c64df-5357-4685-9658-682bbf276058'	System	25 Sep 2020 16:29:11
User entered 'No interference with activity (1)'	System	25 Sep 2020 16:29:11

US3112389

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:14:10

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-09-25T09:28:31', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: 'eb7c64df-5357-4685-9658-682bbf276058' User entered 'None (0)'	System	25 Sep 2020 16:29:11
	System	25 Sep 2020 16:29:11

US3112389

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:14:10

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-09-25T09:28:38', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: 'eb7c64df-5357-4685-9658-682bbf276058' User entered 'None (0)'	System	25 Sep 2020 16:29:11
	System	25 Sep 2020 16:29:11

US3112389

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:14:10

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-09-25T09:28:43', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: 'eb7c64df-5357-4685-9658-682bbf276058' User entered 'None (0)'	System	25 Sep 2020 16:29:11
	System	25 Sep 2020 16:29:11

US3112389

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:14:10

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-09-25T09:28:49', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: 'eb7c64df-5357-4685-9658-682bbf276058' User entered 'None (0)'	System	25 Sep 2020 16:29:11
	System	25 Sep 2020 16:29:11

US3112389

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:14:10

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)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-09-25T09:28:56', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: 'eb7c64df-5357-4685-9658-682bbf276058' User entered 'No (N)'	System	25 Sep 2020 16:29:11
	System	25 Sep 2020 16:29:11

US3112389

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:14:10

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-09-25T09:29:06', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: 'eb7c64df-5357-4685-9658-682bbf276058' User entered '25 Sep 2020 09:29'	System	25 Sep 2020 16:29:11
	System	25 Sep 2020 16:29:11

US3112389

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:14:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
User entered '24 Sep 2020 12:00'	System	23 Sep 2020 22:30:48

US3112389

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:14:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
User entered '25 Sep 2020 11:59'	System	23 Sep 2020 22:30:48

US3112389

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
Data entry locked.	System	23 Sep 2020 22:30:48
User entered 'Day 3'	System	23 Sep 2020 22:30:48

US3112389

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:14:10

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-09-25T12:38:41', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: 'a0229e66-b69e-425f-9741-83c5fea5deb5' User entered 'None (0)'	System	25 Sep 2020 19:39:11
	System	25 Sep 2020 19:39:11

US3112389

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:14:10

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-09-25T12:38:46', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: 'a0229e66-b69e-425f-9741-83c5fea5deb5'	System	25 Sep 2020 19:39:11
User entered 'No interference with activity (1)'	System	25 Sep 2020 19:39:11

US3112389

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:14:10

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-09-25T12:38:50', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: 'a0229e66-b69e-425f-9741-83c5fea5deb5' User entered 'None (0)'	System	25 Sep 2020 19:39:11
	System	25 Sep 2020 19:39:11

US3112389

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:14:10

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-09-25T12:38:54', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: 'a0229e66-b69e-425f-9741-83c5fea5deb5' User entered 'None (0)'	System	25 Sep 2020 19:39:11
	System	25 Sep 2020 19:39:11

US3112389

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:14:10

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-09-25T12:38:57', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: 'a0229e66-b69e-425f-9741-83c5fea5deb5' User entered 'None (0)'	System	25 Sep 2020 19:39:11
	System	25 Sep 2020 19:39:11

US3112389

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:14:10

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-09-25T12:39:02', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: 'a0229e66-b69e-425f-9741-83c5fea5deb5' User entered 'None (0)'	System	25 Sep 2020 19:39:11
	System	25 Sep 2020 19:39:11

US3112389

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:14:10

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)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-09-25T12:39:05', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: 'a0229e66-b69e-425f-9741-83c5fea5deb5' User entered 'No (N)'	System	25 Sep 2020 19:39:11
	System	25 Sep 2020 19:39:11

US3112389

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:14:10

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-09-25T12:39:08', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: 'a0229e66-b69e-425f-9741-83c5fea5deb5' User entered '25 Sep 2020 12:39'	System	25 Sep 2020 19:39:11
	System	25 Sep 2020 19:39:11

US3112389

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:14:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
User entered '25 Sep 2020 12:00'	System	23 Sep 2020 22:30:48

US3112389

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:14:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
User entered '26 Sep 2020 11:59'	System	23 Sep 2020 22:30:48

US3112389

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
Data entry locked.	System	23 Sep 2020 22:30:48
User entered 'Day 4'	System	23 Sep 2020 22:30:48

US3112389

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:14:10

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-09-26T12:53:55', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '5bbcf996-2177-4295-8879-18a4ca455430' User entered 'None (0)'	System	26 Sep 2020 19:54:50
	System	26 Sep 2020 19:54:50

US3112389

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:14:10

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-09-26T12:54:04', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '5bbcf996-2177-4295-8879-18a4ca455430' User entered 'None (0)'	System	26 Sep 2020 19:54:50
	System	26 Sep 2020 19:54:50

US3112389

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:14:10

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-09-26T12:54:09', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '5bbcf996-2177-4295-8879-18a4ca455430' User entered 'None (0)'	System	26 Sep 2020 19:54:50
	System	26 Sep 2020 19:54:50

US3112389

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:14:10

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-09-26T12:54:14', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '5bbcf996-2177-4295-8879-18a4ca455430' User entered 'None (0)'	System	26 Sep 2020 19:54:50
	System	26 Sep 2020 19:54:50

US3112389

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:14:10

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-09-26T12:54:17', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '5bbcf996-2177-4295-8879-18a4ca455430' User entered 'None (0)'	System	26 Sep 2020 19:54:50
	System	26 Sep 2020 19:54:50

US3112389

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:14:10

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-09-26T12:54:23', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '5bbcf996-2177-4295-8879-18a4ca455430' User entered 'None (0)'	System	26 Sep 2020 19:54:50
	System	26 Sep 2020 19:54:50

US3112389

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:14:10

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)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-09-26T12:54:40', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '5bbcf996-2177-4295-8879-18a4ca455430' User entered 'No (N)'	System	26 Sep 2020 19:54:50
	System	26 Sep 2020 19:54:50

US3112389

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:14:10

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-09-26T12:54:48', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '5bbcf996-2177-4295-8879-18a4ca455430' User entered '26 Sep 2020 12:54'	System	26 Sep 2020 19:54:50
	System	26 Sep 2020 19:54:50

US3112389

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:14:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
User entered '26 Sep 2020 12:00'	System	23 Sep 2020 22:30:48

US3112389

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:14:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
User entered '27 Sep 2020 11:59'	System	23 Sep 2020 22:30:48

US3112389

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
Data entry locked.	System	23 Sep 2020 22:30:48
User entered 'Day 5'	System	23 Sep 2020 22:30:48

US3112389

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:14:10

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-09-28T06:33:36', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '68606e24-a90f-48fd-9ab9-51ff25447783' User entered 'None (0)'	System	28 Sep 2020 13:34:42
	System	28 Sep 2020 13:34:42

US3112389

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:14:10

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-09-28T06:34:09', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '68606e24-a90f-48fd-9ab9-51ff25447783'	System	28 Sep 2020 13:34:42
User entered 'No interference with activity (1)'	System	28 Sep 2020 13:34:42

US3112389

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:14:10

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-09-28T06:34:13', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '68606e24-a90f-48fd-9ab9-51ff25447783' User entered 'None (0)'	System	28 Sep 2020 13:34:42
	System	28 Sep 2020 13:34:42

US3112389

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:14:10

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-09-28T06:34:17', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '68606e24-a90f-48fd-9ab9-51ff25447783' User entered 'None (0)'	System	28 Sep 2020 13:34:42
	System	28 Sep 2020 13:34:42

US3112389

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:14:10

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-09-28T06:34:21', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '68606e24-a90f-48fd-9ab9-51ff25447783' User entered 'None (0)'	System	28 Sep 2020 13:34:42
	System	28 Sep 2020 13:34:42

US3112389

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:14:10

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-09-28T06:34:25', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '68606e24-a90f-48fd-9ab9-51ff25447783' User entered 'None (0)'	System	28 Sep 2020 13:34:42
	System	28 Sep 2020 13:34:42

US3112389

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:14:10

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)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-09-28T06:34:31', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '68606e24-a90f-48fd-9ab9-51ff25447783' User entered 'No (N)'	System	28 Sep 2020 13:34:42
	System	28 Sep 2020 13:34:42

US3112389

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:14:10

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-09-28T06:34:39', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '68606e24-a90f-48fd-9ab9-51ff25447783' User entered '28 Sep 2020 06:34'	System	28 Sep 2020 13:34:42
	System	28 Sep 2020 13:34:42

US3112389

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:14:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
User entered '27 Sep 2020 12:00'	System	23 Sep 2020 22:30:48

US3112389

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:14:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
User entered '28 Sep 2020 11:59'	System	23 Sep 2020 22:30:48

US3112389

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
Data entry locked.	System	23 Sep 2020 22:30:48
User entered 'Day 6'	System	23 Sep 2020 22:30:48

US3112389

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:14:10

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-09-29T09:08:24', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: 'a25b91d4-9f90-45a1-8d53-a78910093b4c' User entered 'None (0)'	System	29 Sep 2020 16:09:14
	System	29 Sep 2020 16:09:14

US3112389

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:14:10

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-09-29T09:08:28', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: 'a25b91d4-9f90-45a1-8d53-a78910093b4c' User entered 'None (0)'	System	29 Sep 2020 16:09:14
	System	29 Sep 2020 16:09:14

US3112389

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:14:10

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-09-29T09:08:37', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: 'a25b91d4-9f90-45a1-8d53-a78910093b4c' User entered 'None (0)'	System	29 Sep 2020 16:09:14
	System	29 Sep 2020 16:09:14

US3112389

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:14:10

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-09-29T09:08:52', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: 'a25b91d4-9f90-45a1-8d53-a78910093b4c' User entered 'None (0)'	System	29 Sep 2020 16:09:14
	System	29 Sep 2020 16:09:14

US3112389

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:14:10

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-09-29T09:09:00', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: 'a25b91d4-9f90-45a1-8d53-a78910093b4c' User entered 'None (0)'	System	29 Sep 2020 16:09:14
	System	29 Sep 2020 16:09:14

US3112389

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:14:10

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-09-29T09:09:02', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: 'a25b91d4-9f90-45a1-8d53-a78910093b4c' User entered 'None (0)'	System	29 Sep 2020 16:09:14
	System	29 Sep 2020 16:09:14

US3112389

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:14:10

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)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-09-29T09:09:06', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: 'a25b91d4-9f90-45a1-8d53-a78910093b4c' User entered 'No (N)'	System	29 Sep 2020 16:09:14
	System	29 Sep 2020 16:09:14

US3112389

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:14:10

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-09-29T09:09:11', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: 'a25b91d4-9f90-45a1-8d53-a78910093b4c' User entered '29 Sep 2020 09:09'	System	29 Sep 2020 16:09:14
	System	29 Sep 2020 16:09:14

US3112389

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:14:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
User entered '28 Sep 2020 12:00'	System	23 Sep 2020 22:30:48

US3112389

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:14:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
User entered '29 Sep 2020 11:59'	System	23 Sep 2020 22:30:48

US3112389

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
Data entry locked.	System	23 Sep 2020 22:30:48
User entered 'Day 7'	System	23 Sep 2020 22:30:48

US3112389

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:14:10

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-09-30T06:54:07', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '23199be3-7ad3-4fa5-b911-41480afef2ed' User entered 'None (0)'	System	30 Sep 2020 13:54:51
	System	30 Sep 2020 13:54:51

US3112389

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:14:10

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-09-30T06:54:12', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '23199be3-7ad3-4fa5-b911-41480afef2ed'	System	30 Sep 2020 13:54:51
User entered 'No interference with activity (1)'	System	30 Sep 2020 13:54:51

US3112389

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:14:10

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-09-30T06:54:15', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '23199be3-7ad3-4fa5-b911-41480afef2ed' User entered 'None (0)'	System	30 Sep 2020 13:54:51
	System	30 Sep 2020 13:54:51

US3112389

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:14:10

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-09-30T06:54:19', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '23199be3-7ad3-4fa5-b911-41480afef2ed' User entered 'None (0)'	System	30 Sep 2020 13:54:51
	System	30 Sep 2020 13:54:51

US3112389

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:14:10

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-09-30T06:54:23', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '23199be3-7ad3-4fa5-b911-41480afef2ed' User entered 'None (0)'	System	30 Sep 2020 13:54:51
	System	30 Sep 2020 13:54:51

US3112389

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:14:10

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-09-30T06:54:26', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '23199be3-7ad3-4fa5-b911-41480afef2ed' User entered 'None (0)'	System	30 Sep 2020 13:54:51
	System	30 Sep 2020 13:54:51

US3112389

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:14:10

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)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-09-30T06:54:29', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '23199be3-7ad3-4fa5-b911-41480afef2ed' User entered 'No (N)'	System	30 Sep 2020 13:54:51
	System	30 Sep 2020 13:54:51

US3112389

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:14:10

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-09-30T06:54:47', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '23199be3-7ad3-4fa5-b911-41480afef2ed' User entered '30 Sep 2020 06:54'	System	30 Sep 2020 13:54:51
	System	30 Sep 2020 13:54:51

US3112389

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:14:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
User entered '29 Sep 2020 12:00'	System	23 Sep 2020 22:30:48

US3112389

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:14:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
User entered '30 Sep 2020 11:59'	System	23 Sep 2020 22:30:48

US3112389

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
Data entry locked.	System	30 Sep 2020 13:54:51
User entered 'Day 8'	System	30 Sep 2020 13:54:51

US3112389

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 15:14:10

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-09-30T14:32:16', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '58314750-7362-40ee-bd94-3268680b4527' User entered 'None (0)'	System	30 Sep 2020 21:32:25
	System	30 Sep 2020 21:32:25

US3112389

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 15:14:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-09-30T14:32:22', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '58314750-7362-40ee-bd94-3268680b4527' User entered '30 Sep 2020 14:32'	System	30 Sep 2020 21:32:25
	System	30 Sep 2020 21:32:25

US3112389

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 15:14:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
User entered '30 Sep 2020 12:00'	System	30 Sep 2020 13:54:51

US3112389

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 15:14:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
User entered '01 Oct 2020 11:59'	System	30 Sep 2020 13:54:51

US3112389

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
Data entry locked.	System	30 Sep 2020 13:54:51
User entered 'Day 8'	System	30 Sep 2020 13:54:51

US3112389

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:14:10

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)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-09-30T14:32:28', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: 'ee6983a9-46b2-43e6-aa09-96f71125f02e' User entered 'No (N)'	System	30 Sep 2020 21:32:36
	System	30 Sep 2020 21:32:36

US3112389

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:14:10

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-09-30T14:32:33', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: 'ee6983a9-46b2-43e6-aa09-96f71125f02e' User entered '30 Sep 2020 14:32'	System	30 Sep 2020 21:32:36
	System	30 Sep 2020 21:32:36

US3112389

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:14:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
User entered '30 Sep 2020 12:00'	System	30 Sep 2020 13:54:51

US3112389

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:14:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
User entered '01 Oct 2020 11:59'	System	30 Sep 2020 13:54:51

US3112389

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:14:10

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 22:01:20
User entered 'Yes (Y)'	(b) (4) Matthew Musikanth (b) (4)	30 Sep 2020 18:04:35

US3112389

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:14:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 22:01:20
User entered '30 Sep 2020'	(b) (4) Matthew Musikanth (b) (4)	30 Sep 2020 18:04:35

US3112389

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:14:10

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 22:01:20
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Matthew Musikanth (b) (4)	30 Sep 2020 18:04:35

US3112389

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:14:10

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 22:01:20
User entered empty.	(b) (4) Matthew Musikanth (b) (4)	30 Sep 2020 18:04:35

US3112389

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:14:10

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 22:01:20
User entered 'Yes (Y)'	(b) (4) Matthew Musikanth (b) (4)	30 Sep 2020 18:04:38

US3112389

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:14:10

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User entered 'I'	System	30 Sep 2020 18:04:38

US3112389

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:14:10

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 22:01:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 00:21:10

US3112389

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:14:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 22:01:20
User entered '7 Oct 2020'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 00:21:10

US3112389

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:14:10

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 22:01:20
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 00:21:10

US3112389

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:14:10

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 22:01:20
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 00:21:10

US3112389

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:14:10

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 22:01:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 00:21:14

US3112389

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:14:10

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User entered 'I'	System	08 Oct 2020 00:21:14

US3112389

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:14:10

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 22:01:20
User entered 'Yes (Y)'	Natalie Moy (b) (4)	14 Oct 2020 18:30:22

US3112389

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:14:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 22:01:20
User entered '14 Oct 2020'	(b) (4) Natalie Moy (b) (4)	14 Oct 2020 18:30:22

US3112389

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:14:10

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 22:01:20
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Natalie Moy (b) (4)	14 Oct 2020 18:30:22

US3112389

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:14:10

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 22:01:20
User entered empty.	(b) (4) Natalie Moy (b) (4)	14 Oct 2020 18:30:22

US3112389

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:14:10

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 22:01:20
User entered 'Yes (Y)'	Natalie Moy (b) (4)	14 Oct 2020 18:30:31

US3112389

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:14:10

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User entered 'I'	System	14 Oct 2020 18:30:31

US3112389

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:14:10

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 22:01:20
User entered 'Yes (Y)'	Natalie Moy (b) (4)	22 Oct 2020 23:14:39

US3112389

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:14:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 22:01:20
User entered '22 Oct 2020'	(b) (4) Natalie Moy (b) (4)	22 Oct 2020 23:14:39

US3112389

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:14:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 22:01:20
User entered 'Clinic (Clinic)'	Natalie Moy (b) (4)	22 Oct 2020 23:14:39

US3112389

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:14:10

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User entered 'VISIT3'	System	22 Oct 2020 23:14:39

US3112389

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:14:10

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 22:01:20
User entered 'Yes (Y)'	Natalie Moy (b) (4)	22 Oct 2020 23:15:13

US3112389

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:14:10

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 22:01:20
User entered '22 Oct 2020'	(b) (4) Natalie Moy (b) (4)	22 Oct 2020 23:15:13

US3112389

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:14:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 22:01:20
User entered '14:21'	Natalie Moy (b) (4)	22 Oct 2020 23:15:13

US3112389

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:14:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User entered '22 Oct 2020 14:21'	System	22 Oct 2020 23:15:13

US3112389

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:14:10

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 22:01:20
User entered '98.3' F	(b) (4) Natalie Moy (b) (4)	22 Oct 2020 23:15:13

US3112389

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:14:10

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 22:01:20
User entered 'Oral (Oral)'	(b) (4) Natalie Moy (b) (4)	22 Oct 2020 23:15:13

US3112389

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:14:10

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 22:01:20
User entered empty.	(b) (4) Natalie Moy (b) (4)	22 Oct 2020 23:15:13

US3112389

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:14:10

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 22:01:20
User entered '79'	Natalie Moy (b) (4)	22 Oct 2020 23:15:13

US3112389

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:14:10

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User entered 'bpm'	System	22 Oct 2020 23:15:13

US3112389

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:14:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 22:01:20
User entered '16'	Natalie Moy (b) (4)	22 Oct 2020 23:15:13

US3112389

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:14:10

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User entered 'breaths/min'	System	22 Oct 2020 23:15:13

US3112389

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:14:10

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 22:01:20
User entered '111'	Natalie Moy (b) (4)	22 Oct 2020 23:15:13

US3112389

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:14:10

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User entered 'mmHg'	System	22 Oct 2020 23:15:13

US3112389

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:14:10

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 22:01:20
User entered '77'	Natalie Moy (b) (4)	22 Oct 2020 23:15:13

US3112389

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:14:10

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User entered 'mmHg'	System	22 Oct 2020 23:15:13

US3112389

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:14:10

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17

US3112389

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:14:10

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17

US3112389

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:14:10

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 22:01:20
User entered 'No (N)'	Natalie Moy (b) (4)	22 Oct 2020 23:15:22

US3112389

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:14:10

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 22:01:20
User entered empty.	(b) (4) Natalie Moy (b) (4)	22 Oct 2020 23:15:22

US3112389

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:14:10

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 22:01:20
User entered 'Yes (Y)'	Natalie Moy (b) (4)	22 Oct 2020 23:15:35

US3112389

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:14:10

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 22:01:20
User entered '22 Oct 2020'	(b) (4) Natalie Moy (b) (4)	22 Oct 2020 23:15:35

US3112389

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:14:10

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 22:01:20
User entered '14:30'	Natalie Moy (b) (4)	22 Oct 2020 23:15:35

US3112389

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:14:10

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User entered '22 Oct 2020 14:30'	System	22 Oct 2020 23:15:35

US3112389

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:14:10

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 22:01:20
User entered 'Yes (Y)'	(b) (4) Natalie Moy (b) (4)	22 Oct 2020 23:15:38

US3112389

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:14:10

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User entered 'I'	System	22 Oct 2020 23:15:38

US3112389

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
Data entry locked.	System	26 Aug 2020 23:03:15
User entered 'Day 64'	System	26 Aug 2020 23:03:15

US3112389

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[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)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-10-26T07:02:36', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '0d4a30d8-e160-415f-9d68-3b32b4ced4c4' User entered 'No (N)'	System	26 Oct 2020 14:05:13
	System	26 Oct 2020 14:05:13

US3112389

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Have you been exposed to someone with 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)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-10-26T07:03:46', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '0d4a30d8-e160-415f-9d68-3b32b4ced4c4'	System	26 Oct 2020 14:05:13
User entered 'No (N)'	System	26 Oct 2020 14:05:13

US3112389

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-10-26T07:05:09', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '0d4a30d8-e160-415f-9d68-3b32b4ced4c4' User entered '26 Oct 2020 07:05:09'	System	26 Oct 2020 14:05:13
	System	26 Oct 2020 14:05:13

US3112389

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
Data entry locked.	System	26 Aug 2020 23:03:15
User entered '26 Oct 2020 00:01'	System	26 Aug 2020 23:03:15

US3112389

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
Data entry locked.	System	26 Aug 2020 23:03:15
User entered '30 Oct 2020 23:59'	System	26 Aug 2020 23:03:15

US3112389

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
Data entry locked.	System	26 Aug 2020 23:03:15
User entered 'Day 71'	System	26 Aug 2020 23:03:15

US3112389

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[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)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-11-02T16:41:41', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '7a91f5b0-7c91-45d7-93bd-f2e0ca65bbb5' User entered 'No (N)'	System	03 Nov 2020 00:42:05
	System	03 Nov 2020 00:42:05

US3112389

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

Have you been exposed to someone with 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)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-11-02T16:41:49', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '7a91f5b0-7c91-45d7-93bd-f2e0ca65bbb5'	System	03 Nov 2020 00:42:05
User entered 'No (N)'	System	03 Nov 2020 00:42:05

US3112389

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-11-02T16:42:00', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '7a91f5b0-7c91-45d7-93bd-f2e0ca65bbb5' User entered '02 Nov 2020 16:42:00'	System	03 Nov 2020 00:42:05
	System	03 Nov 2020 00:42:05

US3112389

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
Data entry locked.	System	26 Aug 2020 23:03:15
User entered '02 Nov 2020 00:01'	System	26 Aug 2020 23:03:15

US3112389

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
Data entry locked.	System	26 Aug 2020 23:03:15
User entered '06 Nov 2020 23:59'	System	26 Aug 2020 23:03:15

US3112389

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
Data entry locked.	System	26 Aug 2020 23:03:15
User entered 'Day 78'	System	26 Aug 2020 23:03:15

US3112389

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[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)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-11-10T05:28:20', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '3487b06b-42d3-40c0-90af-ae6501d848c7' User entered 'No (N)'	System	10 Nov 2020 13:28:44
	System	10 Nov 2020 13:28:44

US3112389

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

Have you been exposed to someone with 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)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-11-10T05:28:32', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '3487b06b-42d3-40c0-90af-ae6501d848c7' User entered 'No (N)'	System	10 Nov 2020 13:28:44
	System	10 Nov 2020 13:28:44

US3112389

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-11-10T05:28:42', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '3487b06b-42d3-40c0-90af-ae6501d848c7' User entered '10 Nov 2020 05:28:42'	System	10 Nov 2020 13:28:44
	System	10 Nov 2020 13:28:44

US3112389

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
Data entry locked.	System	26 Aug 2020 23:03:15
User entered '09 Nov 2020 00:01'	System	26 Aug 2020 23:03:15

US3112389

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:50:12
Data entry locked.	System	26 Aug 2020 23:03:15
User entered '13 Nov 2020 23:59'	System	26 Aug 2020 23:03:15

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[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 (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-11-23T10:18:04', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '0032f53b-80c0-4636-93fe-5a858d0ff87d' User entered 'No (N)'	System	23 Nov 2020 18:18:24
	System	23 Nov 2020 18:18:24

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

Have you been exposed to someone with 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 (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-11-23T10:18:14', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '0032f53b-80c0-4636-93fe-5a858d0ff87d' User entered 'No (N)'	System	23 Nov 2020 18:18:24

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-11-23T10:18:22', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '0032f53b-80c0-4636-93fe-5a858d0ff87d' User entered '23 Nov 2020 10:18:22'	System	23 Nov 2020 18:18:24
	System	23 Nov 2020 18:18:24

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '20 Nov 2020 00:01'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '24 Nov 2020 23:59'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[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 (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-11-30T08:00:44', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '8b467d17-b3a3-4d9c-8ab1-095e87d4bf05'	System	30 Nov 2020 16:01:08
User entered 'No (N)'	System	30 Nov 2020 16:01:08

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

Have you been exposed to someone with 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 (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-11-30T08:00:53', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '8b467d17-b3a3-4d9c-8ab1-095e87d4bf05'	System	30 Nov 2020 16:01:08
User entered 'No (N)'	System	30 Nov 2020 16:01:08

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-11-30T08:01:03', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '8b467d17-b3a3-4d9c-8ab1-095e87d4bf05' User entered '30 Nov 2020 08:01:03'	System	30 Nov 2020 16:01:08
	System	30 Nov 2020 16:01:08

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '27 Nov 2020 00:01'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '01 Dec 2020 23:59'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[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 (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-12-04T08:45:14', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '9f832c6b-e0e0-4da6-a548-085f0500d100'	System	04 Dec 2020 16:47:22
User entered 'No (N)'	System	04 Dec 2020 16:47:22

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

Have you been exposed to someone with 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 (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-12-04T08:46:32', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '9f832c6b-e0e0-4da6-a548-085f0500d100'	System	04 Dec 2020 16:47:22
User entered 'No (N)'	System	04 Dec 2020 16:47:22

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF02E634-9162-4DF8-AAA8-B53F93F84DA4)', Time: '2020-12-04T08:47:17', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '9f832c6b-e0e0-4da6-a548-085f0500d100' User entered '04 Dec 2020 08:47:17'	System	04 Dec 2020 16:47:22
	System	04 Dec 2020 16:47:22

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '04 Dec 2020 00:01'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '08 Dec 2020 23:59'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '11 Dec 2020 00:01'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '15 Dec 2020 23:59'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '18 Dec 2020 00:01'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '22 Dec 2020 23:59'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '25 Dec 2020 00:01'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '29 Dec 2020 23:59'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '01 Jan 2021 00:01'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '05 Jan 2021 23:59'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[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 (2F347F05-3068-407C-9566-C2A28F89E578)', Time: '2021-01-08T09:35:19', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '5d4ed581-610b-43a0-9ad0-c1c4b094ed97'	System	08 Jan 2021 17:35:37
User entered 'No (N)'	System	08 Jan 2021 17:35:37

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

Have you been exposed to someone with 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 (2F347F05-3068-407C-9566-C2A28F89E578)', Time: '2021-01-08T09:35:25', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '5d4ed581-610b-43a0-9ad0-c1c4b094ed97'	System	08 Jan 2021 17:35:37
User entered 'No (N)'	System	08 Jan 2021 17:35:37

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F347F05-3068-407C-9566-C2A28F89E578)', Time: '2021-01-08T09:35:32', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '5d4ed581-610b-43a0-9ad0-c1c4b094ed97' User entered '08 Jan 2021 09:35:32'	System	08 Jan 2021 17:35:37
	System	08 Jan 2021 17:35:37

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '08 Jan 2021 00:01'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '12 Jan 2021 23:59'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[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 (2F347F05-3068-407C-9566-C2A28F89E578)', Time: '2021-01-19T12:18:04', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '88c0e91f-7d8d-4bc5-8c81-c84413996857' User entered 'Yes (Y)'	System	19 Jan 2021 20:18:57

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

Have you been exposed to someone with 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 (2F347F05-3068-407C-9566-C2A28F89E578)', Time: '2021-01-19T12:18:11', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '88c0e91f-7d8d-4bc5-8c81-c84413996857'	System	19 Jan 2021 20:18:57
User entered 'No (N)'	System	19 Jan 2021 20:18:57

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[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 (2F347F05-3068-407C-9566-C2A28F89E578)', Time: '2021-01-19T12:18:20', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '88c0e91f-7d8d-4bc5-8c81-c84413996857' User entered 'No (N)'	System	19 Jan 2021 20:18:57
	System	19 Jan 2021 20:18:57

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[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 (2F347F05-3068-407C-9566-C2A28F89E578)', Time: '2021-01-19T12:18:31', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '88c0e91f-7d8d-4bc5-8c81-c84413996857' User entered 'Yes (Y)'	System	19 Jan 2021 20:18:57
	System	19 Jan 2021 20:18:57

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Please 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 (2F347F05-3068-407C-9566-C2A28F89E578)', Time: '2021-01-19T12:18:41', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '88c0e91f-7d8d-4bc5-8c81-c84413996857'	System	19 Jan 2021 20:18:57
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	19 Jan 2021 20:18:57

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F347F05-3068-407C-9566-C2A28F89E578)', Time: '2021-01-19T12:18:46', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '88c0e91f-7d8d-4bc5-8c81-c84413996857' User entered '19 Jan 2021 12:18:46'	System	19 Jan 2021 20:18:57
	System	19 Jan 2021 20:18:57

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '15 Jan 2021 00:01'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '19 Jan 2021 23:59'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[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 (2F347F05-3068-407C-9566-C2A28F89E578)', Time: '2021-01-23T09:32:42', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: 'cbd526a1-c38a-45ab-aa25-879da69f44d7' User entered 'No (N)'	System	23 Jan 2021 17:32:54
	System	23 Jan 2021 17:32:54

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

Have you been exposed to someone with 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 (2F347F05-3068-407C-9566-C2A28F89E578)', Time: '2021-01-23T09:32:46', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: 'cbd526a1-c38a-45ab-aa25-879da69f44d7'	System	23 Jan 2021 17:32:54
User entered 'No (N)'	System	23 Jan 2021 17:32:54

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F347F05-3068-407C-9566-C2A28F89E578)', Time: '2021-01-23T09:32:51', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: 'cbd526a1-c38a-45ab-aa25-879da69f44d7' User entered '23 Jan 2021 09:32:51'	System	23 Jan 2021 17:32:54
	System	23 Jan 2021 17:32:54

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '22 Jan 2021 00:01'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '26 Jan 2021 23:59'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[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 (2F347F05-3068-407C-9566-C2A28F89E578)', Time: '2021-01-31T06:58:32', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '5a2daa64-20d0-481d-a222-bea5031cfad1' User entered 'No (N)'	System	31 Jan 2021 14:58:49
	System	31 Jan 2021 14:58:49

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

Have you been exposed to someone with 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 (2F347F05-3068-407C-9566-C2A28F89E578)', Time: '2021-01-31T06:58:40', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '5a2daa64-20d0-481d-a222-bea5031cfad1' User entered 'No (N)'	System	31 Jan 2021 14:58:49
	System	31 Jan 2021 14:58:49

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F347F05-3068-407C-9566-C2A28F89E578)', Time: '2021-01-31T06:58:47', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '5a2daa64-20d0-481d-a222-bea5031cfad1' User entered '31 Jan 2021 06:58:47'	System	31 Jan 2021 14:58:49
	System	31 Jan 2021 14:58:49

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '29 Jan 2021 00:01'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '02 Feb 2021 23:59'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[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 (2F347F05-3068-407C-9566-C2A28F89E578)', Time: '2021-02-09T04:36:50', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: 'faf1e0fe-973b-4b49-84ab-e1cefa9029d5'	System	09 Feb 2021 12:37:11
User entered 'No (N)'	System	09 Feb 2021 12:37:11

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

Have you been exposed to someone with 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 (2F347F05-3068-407C-9566-C2A28F89E578)', Time: '2021-02-09T04:36:59', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: 'faf1e0fe-973b-4b49-84ab-e1cefa9029d5'	System	09 Feb 2021 12:37:11
User entered 'No (N)'	System	09 Feb 2021 12:37:11

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F347F05-3068-407C-9566-C2A28F89E578)', Time: '2021-02-09T04:37:07', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: 'faf1e0fe-973b-4b49-84ab-e1cefa9029d5' User entered '09 Feb 2021 04:37:07'	System	09 Feb 2021 12:37:11
	System	09 Feb 2021 12:37:11

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '05 Feb 2021 00:01'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '09 Feb 2021 23:59'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[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 (2F347F05-3068-407C-9566-C2A28F89E578)', Time: '2021-02-14T12:15:00', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '1709b030-b093-498e-818e-c7b6be8b99a1'	System	14 Feb 2021 20:15:18
User entered 'No (N)'	System	14 Feb 2021 20:15:18

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Have you been exposed to someone with 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 (2F347F05-3068-407C-9566-C2A28F89E578)', Time: '2021-02-14T12:15:08', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '1709b030-b093-498e-818e-c7b6be8b99a1'	System	14 Feb 2021 20:15:18
User entered 'No (N)'	System	14 Feb 2021 20:15:18

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F347F05-3068-407C-9566-C2A28F89E578)', Time: '2021-02-14T12:15:15', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '1709b030-b093-498e-818e-c7b6be8b99a1'	System	14 Feb 2021 20:15:18
User entered '14 Feb 2021 12:15:15'	System	14 Feb 2021 20:15:18

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '12 Feb 2021 00:01'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '16 Feb 2021 23:59'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[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 (2F347F05-3068-407C-9566-C2A28F89E578)', Time: '2021-02-19T01:08:08', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: 'b092f0c7-7e04-4cf0-bf4f-fd267a538724' User entered 'No (N)'	System	19 Feb 2021 09:08:26
	System	19 Feb 2021 09:08:26

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Have you been exposed to someone with 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 (2F347F05-3068-407C-9566-C2A28F89E578)', Time: '2021-02-19T01:08:14', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: 'b092f0c7-7e04-4cf0-bf4f-fd267a538724' User entered 'No (N)'	System	19 Feb 2021 09:08:26
	System	19 Feb 2021 09:08:26

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F347F05-3068-407C-9566-C2A28F89E578)', Time: '2021-02-19T01:08:23', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: 'b092f0c7-7e04-4cf0-bf4f-fd267a538724' User entered '19 Feb 2021 01:08:23'	System	19 Feb 2021 09:08:26
	System	19 Feb 2021 09:08:26

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '19 Feb 2021 00:01'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '23 Feb 2021 23:59'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[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 (2F347F05-3068-407C-9566-C2A28F89E578)', Time: '2021-02-26T08:58:09-08:00', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '752dd9cf-d3f3-4f22-8e79-90c85f009183'	System	26 Feb 2021 16:58:25
User entered 'No (N)'	System	26 Feb 2021 16:58:25

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

Have you been exposed to someone with 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 (2F347F05-3068-407C-9566-C2A28F89E578)', Time: '2021-02-26T08:58:15-08:00', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '752dd9cf-d3f3-4f22-8e79-90c85f009183'	System	26 Feb 2021 16:58:25
User entered 'No (N)'	System	26 Feb 2021 16:58:25

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F347F05-3068-407C-9566-C2A28F89E578)', Time: '2021-02-26T08:58:21-08:00', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '752dd9cf-d3f3-4f22-8e79-90c85f009183'	System	26 Feb 2021 16:58:25
User entered '26 Feb 2021 16:58:21'	System	26 Feb 2021 16:58:25

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '26 Feb 2021 00:01'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '02 Mar 2021 23:59'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[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 (2F347F05-3068-407C-9566-C2A28F89E578)', Time: '2021-03-07T12:12:00-08:00', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: 'a8071e97-61c3-43b0-9b83-90e9b387912d'	System	07 Mar 2021 20:12:15
User entered 'No (N)'	System	07 Mar 2021 20:12:15

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

Have you been exposed to someone with 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 (2F347F05-3068-407C-9566-C2A28F89E578)', Time: '2021-03-07T12:12:08-08:00', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: 'a8071e97-61c3-43b0-9b83-90e9b387912d'	System	07 Mar 2021 20:12:15
User entered 'No (N)'	System	07 Mar 2021 20:12:15

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F347F05-3068-407C-9566-C2A28F89E578)', Time: '2021-03-07T12:12:13-08:00', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: 'a8071e97-61c3-43b0-9b83-90e9b387912d' User entered '07 Mar 2021 12:12:13'	System	07 Mar 2021 20:12:15
	System	07 Mar 2021 20:12:15

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '05 Mar 2021 00:01'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '09 Mar 2021 23:59'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[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 (2F347F05-3068-407C-9566-C2A28F89E578)', Time: '2021-03-13T10:56:50-08:00', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '6cc040bd-51eb-4ecb-9d51-4102994ab93e'	System	13 Mar 2021 18:57:00
User entered 'No (N)'	System	13 Mar 2021 18:57:00

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Have you been exposed to someone with 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 (2F347F05-3068-407C-9566-C2A28F89E578)', Time: '2021-03-13T10:56:54-08:00', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '6cc040bd-51eb-4ecb-9d51-4102994ab93e'	System	13 Mar 2021 18:57:00
User entered 'No (N)'	System	13 Mar 2021 18:57:00

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F347F05-3068-407C-9566-C2A28F89E578)', Time: '2021-03-13T10:56:58-08:00', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '6cc040bd-51eb-4ecb-9d51-4102994ab93e'	System	13 Mar 2021 18:57:00
User entered '13 Mar 2021 10:56:58'	System	13 Mar 2021 18:57:00

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '12 Mar 2021 00:01'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '16 Mar 2021 23:59'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[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 (2F347F05-3068-407C-9566-C2A28F89E578)', Time: '2021-03-23T08:59:09-07:00', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: 'c518d793-d827-4d8d-8866-d2af19bfbea4'	System	29 Mar 2021 17:58:37
User entered 'No (N)'	System	29 Mar 2021 17:58:37

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

Have you been exposed to someone with 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 (2F347F05-3068-407C-9566-C2A28F89E578)', Time: '2021-03-23T08:58:40-07:00', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: 'c518d793-d827-4d8d-8866-d2af19bfbea4'	System	29 Mar 2021 17:58:37
User entered 'No (N)'	System	29 Mar 2021 17:58:37

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F347F05-3068-407C-9566-C2A28F89E578)', Time: '2021-03-23T08:59:25-07:00', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: 'c518d793-d827-4d8d-8866-d2af19bfbea4'	System	29 Mar 2021 17:58:37
User entered '23 Mar 2021 08:59:25'	System	29 Mar 2021 17:58:37

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '19 Mar 2021 00:01'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '23 Mar 2021 23:59'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[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 (2F347F05-3068-407C-9566-C2A28F89E578)', Time: '2021-03-29T10:58:42-07:00', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '1beba8b1-d4a2-42a6-b4a4-4189bc53703c'	System	29 Mar 2021 17:59:02
User entered 'No (N)'	System	29 Mar 2021 17:59:02

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

Have you been exposed to someone with 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 (2F347F05-3068-407C-9566-C2A28F89E578)', Time: '2021-03-29T10:58:49-07:00', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '1beba8b1-d4a2-42a6-b4a4-4189bc53703c'	System	29 Mar 2021 17:59:02
User entered 'No (N)'	System	29 Mar 2021 17:59:02

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F347F05-3068-407C-9566-C2A28F89E578)', Time: '2021-03-29T10:58:59-07:00', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '1beba8b1-d4a2-42a6-b4a4-4189bc53703c' User entered '29 Mar 2021 10:58:59'	System	29 Mar 2021 17:59:02
	System	29 Mar 2021 17:59:02

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '26 Mar 2021 00:01'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '30 Mar 2021 23:59'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[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 (2F347F05-3068-407C-9566-C2A28F89E578)', Time: '2021-04-02T00:14:28-07:00', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '68c6b736-6390-4c41-894b-fb0a2a79ce99'	System	02 Apr 2021 07:14:40
User entered 'No (N)'	System	02 Apr 2021 07:14:40

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Have you been exposed to someone with 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 (2F347F05-3068-407C-9566-C2A28F89E578)', Time: '2021-04-02T00:14:33-07:00', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '68c6b736-6390-4c41-894b-fb0a2a79ce99'	System	02 Apr 2021 07:14:40
User entered 'No (N)'	System	02 Apr 2021 07:14:40

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F347F05-3068-407C-9566-C2A28F89E578)', Time: '2021-04-02T00:14:38-07:00', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '68c6b736-6390-4c41-894b-fb0a2a79ce99'	System	02 Apr 2021 07:14:40
User entered '02 Apr 2021 00:14:38'	System	02 Apr 2021 07:14:40

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '02 Apr 2021 00:01'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '06 Apr 2021 23:59'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[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 (2F347F05-3068-407C-9566-C2A28F89E578)', Time: '2021-04-13T09:29:33-07:00', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '964e033b-fea2-4a91-bc2f-1fd604b004ce' User entered 'No (N)'	System	13 Apr 2021 16:29:50
	System	13 Apr 2021 16:29:50

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

Have you been exposed to someone with 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 (2F347F05-3068-407C-9566-C2A28F89E578)', Time: '2021-04-13T09:29:42-07:00', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '964e033b-fea2-4a91-bc2f-1fd604b004ce'	System	13 Apr 2021 16:29:50
User entered 'No (N)'	System	13 Apr 2021 16:29:50

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F347F05-3068-407C-9566-C2A28F89E578)', Time: '2021-04-13T09:29:48-07:00', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '964e033b-fea2-4a91-bc2f-1fd604b004ce' User entered '13 Apr 2021 09:29:48'	System	13 Apr 2021 16:29:50
	System	13 Apr 2021 16:29:50

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '09 Apr 2021 00:01'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '13 Apr 2021 23:59'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '16 Apr 2021 00:01'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '20 Apr 2021 23:59'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[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 (2F347F05-3068-407C-9566-C2A28F89E578)', Time: '2021-04-24T08:47:48-05:00', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '2c3e9242-7b68-43ab-be09-1d81d2cdf23'	System	24 Apr 2021 13:48:03
User entered 'No (N)'	System	24 Apr 2021 13:48:03

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Have you been exposed to someone with 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 (2F347F05-3068-407C-9566-C2A28F89E578)', Time: '2021-04-24T08:47:53-05:00', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '2c3e9242-7b68-43ab-be09-1d81d2cdf23'	System	24 Apr 2021 13:48:03
User entered 'No (N)'	System	24 Apr 2021 13:48:03

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F347F05-3068-407C-9566-C2A28F89E578)', Time: '2021-04-24T08:48:00-05:00', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '2c3e9242-7b68-43ab-be09-1d81d2cdfe23'	System	24 Apr 2021 13:48:03
User entered '24 Apr 2021 08:48:00'	System	24 Apr 2021 13:48:03

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '23 Apr 2021 00:01'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '27 Apr 2021 23:59'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '30 Apr 2021 00:01'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '04 May 2021 23:59'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '07 May 2021 00:01'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '11 May 2021 23:59'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '14 May 2021 00:01'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '18 May 2021 23:59'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '21 May 2021 00:01'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '25 May 2021 23:59'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '28 May 2021 00:01'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '01 Jun 2021 23:59'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '04 Jun 2021 00:01'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '08 Jun 2021 23:59'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '11 Jun 2021 00:01'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '15 Jun 2021 23:59'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '18 Jun 2021 00:01'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '22 Jun 2021 23:59'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '25 Jun 2021 00:01'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '29 Jun 2021 23:59'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '02 Jul 2021 00:01'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '06 Jul 2021 23:59'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '09 Jul 2021 00:01'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '13 Jul 2021 23:59'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '16 Jul 2021 00:01'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '20 Jul 2021 23:59'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '23 Jul 2021 00:01'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '27 Jul 2021 23:59'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '30 Jul 2021 00:01'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '03 Aug 2021 23:59'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '06 Aug 2021 00:01'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '10 Aug 2021 23:59'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '13 Aug 2021 00:01'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '17 Aug 2021 23:59'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '20 Aug 2021 00:01'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '24 Aug 2021 23:59'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '27 Aug 2021 00:01'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '31 Aug 2021 23:59'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '03 Sep 2021 00:01'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '07 Sep 2021 23:59'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '10 Sep 2021 00:01'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '14 Sep 2021 23:59'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '17 Sep 2021 00:01'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '21 Sep 2021 23:59'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '24 Sep 2021 00:01'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '28 Sep 2021 23:59'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '01 Oct 2021 00:01'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '05 Oct 2021 23:59'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '08 Oct 2021 00:01'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '12 Oct 2021 23:59'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '15 Oct 2021 00:01'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '19 Oct 2021 23:59'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '22 Oct 2021 00:01'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '26 Oct 2021 23:59'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '29 Oct 2021 00:01'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '02 Nov 2021 23:59'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '05 Nov 2021 00:01'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '09 Nov 2021 23:59'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '12 Nov 2021 00:01'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '16 Nov 2021 23:59'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '19 Nov 2021 00:01'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '23 Nov 2021 23:59'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '26 Nov 2021 00:01'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '30 Nov 2021 23:59'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '03 Dec 2021 00:01'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '07 Dec 2021 23:59'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '10 Dec 2021 00:01'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '14 Dec 2021 23:59'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '17 Dec 2021 00:01'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '21 Dec 2021 23:59'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '24 Dec 2021 00:01'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '28 Dec 2021 23:59'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '31 Dec 2021 00:01'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '04 Jan 2022 23:59'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '07 Jan 2022 00:01'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '11 Jan 2022 23:59'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '14 Jan 2022 00:01'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '18 Jan 2022 23:59'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '21 Jan 2022 00:01'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '25 Jan 2022 23:59'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '28 Jan 2022 00:01'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '01 Feb 2022 23:59'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '04 Feb 2022 00:01'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '08 Feb 2022 23:59'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '11 Feb 2022 00:01'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '15 Feb 2022 23:59'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '18 Feb 2022 00:01'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '22 Feb 2022 23:59'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '25 Feb 2022 00:01'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '01 Mar 2022 23:59'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '04 Mar 2022 00:01'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '08 Mar 2022 23:59'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '11 Mar 2022 00:01'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '15 Mar 2022 23:59'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '18 Mar 2022 00:01'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '22 Mar 2022 23:59'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '25 Mar 2022 00:01'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '29 Mar 2022 23:59'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '01 Apr 2022 00:01'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '05 Apr 2022 23:59'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '08 Apr 2022 00:01'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '12 Apr 2022 23:59'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '15 Apr 2022 00:01'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '19 Apr 2022 23:59'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '22 Apr 2022 00:01'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '26 Apr 2022 23:59'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '29 Apr 2022 00:01'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '03 May 2022 23:59'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '06 May 2022 00:01'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '10 May 2022 23:59'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '13 May 2022 00:01'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '17 May 2022 23:59'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '20 May 2022 00:01'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '24 May 2022 23:59'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '27 May 2022 00:01'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '31 May 2022 23:59'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '03 Jun 2022 00:01'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '07 Jun 2022 23:59'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '10 Jun 2022 00:01'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '14 Jun 2022 23:59'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '17 Jun 2022 00:01'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '21 Jun 2022 23:59'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '24 Jun 2022 00:01'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '28 Jun 2022 23:59'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '01 Jul 2022 00:01'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '05 Jul 2022 23:59'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '08 Jul 2022 00:01'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '12 Jul 2022 23:59'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '15 Jul 2022 00:01'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '19 Jul 2022 23:59'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '22 Jul 2022 00:01'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '26 Jul 2022 23:59'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '29 Jul 2022 00:01'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '02 Aug 2022 23:59'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '05 Aug 2022 00:01'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '09 Aug 2022 23:59'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '12 Aug 2022 00:01'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '16 Aug 2022 23:59'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '19 Aug 2022 00:01'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '23 Aug 2022 23:59'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '26 Aug 2022 00:01'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '30 Aug 2022 23:59'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '02 Sep 2022 00:01'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '06 Sep 2022 23:59'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '09 Sep 2022 00:01'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '13 Sep 2022 23:59'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '16 Sep 2022 00:01'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '20 Sep 2022 23:59'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '23 Sep 2022 00:01'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '27 Sep 2022 23:59'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '30 Sep 2022 00:01'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '04 Oct 2022 23:59'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '07 Oct 2022 00:01'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '11 Oct 2022 23:59'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '14 Oct 2022 00:01'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '18 Oct 2022 23:59'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '21 Oct 2022 00:01'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '25 Oct 2022 23:59'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '28 Oct 2022 00:01'	System	19 Nov 2020 18:37:12

US3112389

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:14:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:37:12
Amendment Manager: User entered '01 Nov 2022 23:59'	System	19 Nov 2020 18:37:12

US3112389

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:14:10

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)	30 Apr 2021 11:30:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F347F05-3068-407C-9566-C2A28F89E578)', Time: '2021-03-07T12:12:28-08:00', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '0f0945e9-1ee6-4530-bc31-e3fccfe44478'	System	07 Mar 2021 20:13:04
User entered 'Yes (Y)'	System	07 Mar 2021 20:13:04

US3112389

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:14:10

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?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:30:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F347F05-3068-407C-9566-C2A28F89E578)', Time: '2021-03-07T12:12:41-08:00', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '0f0945e9-1ee6-4530-bc31-e3fccfe44478'	System	07 Mar 2021 20:13:04
User entered 'No (N)'	System	07 Mar 2021 20:13:04

US3112389

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:14:10

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:30:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F347F05-3068-407C-9566-C2A28F89E578)', Time: '2021-03-07T12:12:54-08:00', User OID: 'PatientReportedOutcome (US3112389)', ODM File OID: '0f0945e9-1ee6-4530-bc31-e3fccfe44478' User entered '07 Mar 2021 12:12:54'	System	07 Mar 2021 20:13:04
	System	07 Mar 2021 20:13:04

US3112389

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:14:10

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 20:00:57
User entered 'Yes (Y)'	(b) (4) Matthew Musikanth (b) (4)	19 Nov 2020 17:07:37

US3112389

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:14:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 20:00:57
User entered '19 Nov 2020'	(b) (4) Matthew Musikanth	19 Nov 2020 17:07:37
	(b) (4)	

US3112389

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:14:10

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 20:00:57
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Matthew Musikanth (b) (4)	19 Nov 2020 17:07:37

US3112389

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:14:10

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 20:00:57
User entered empty.	(b) (4) Matthew Musikanth	19 Nov 2020 17:07:37
	(b) (4)	

US3112389

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:14:10

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 20:00:57
User entered 'Yes (Y)'	(b) (4) Matthew Musikanth	19 Nov 2020 17:07:41
	(b) (4)	

US3112389

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:14:10

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:12:17
User entered 'I'	System	19 Nov 2020 17:07:41

US3112389

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:14:10

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:17:45
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
User entered 'Yes (Y)'	Karen Mylerberg (b) (4) (b) (4)	22 Dec 2020 21:47:13

US3112389

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:14:10

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:17:45
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
User entered '22 Dec 2020'	Karen Mylerberg (b) (4) (b) (4)	22 Dec 2020 21:47:13

US3112389

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:14:10

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:17:45
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
User entered 'Contact Made (CONTACT MADE)'	Karen Mylerberg (b) (4) (b) (4)	22 Dec 2020 21:47:13

US3112389

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:14:10

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:17:45
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
User entered empty.	Karen Mylerberg (b) (4) (b) (4)	22 Dec 2020 21:47:13

US3112389

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:14:10

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:17:45
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
User entered 'Yes (Y)'	Karen Mylerberg (b) (4) (b) (4)	22 Dec 2020 21:47:17

US3112389

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:14:10

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:17:45
User entered 'I'	System	22 Dec 2020 21:47:17

US3112389

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:14:10

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:17:45
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:36
User closed query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	System	19 Feb 2021 16:09:53
User opened query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	System	19 Feb 2021 16:09:27
User entered 'No (N)'	Karen Mylerberg (b) (4) (b) (4)	19 Feb 2021 16:09:27

US3112389

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:14:10

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:17:45
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:36
User entered empty.	Karen Mylerberg (b) (4) (b) (4)	19 Feb 2021 16:09:27

US3112389

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:14:10

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:17:45
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:36
	(b) (4)	
User entered empty; reason for change Data Entry Error	Karen Mylerberg (b) (4)	19 Feb 2021 16:09:53
	(b) (4)	
User entered 'Contact Not Made (CONTACT NOT MADE)'	Karen Mylerberg (b) (4)	19 Feb 2021 16:09:27
	(b) (4)	

US3112389

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:14:10

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:17:45
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:36
	(b) (4)	
User entered 'Subject in convalescent phase'	Karen Mylerberg (b) (4)	19 Feb 2021 16:09:27
	(b) (4)	

US3112389

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:14:10

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:17:45
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
User entered 'Yes (Y)'	Karen Mylerberg (b) (4) (b) (4)	19 Feb 2021 16:10:39

US3112389

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:14:10

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:17:45
User entered 'I'	System	19 Feb 2021 16:10:39

US3112389

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:14:10

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:17:45
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:36
User entered 'Yes (Y)'	Brenda Grande (b) (4) (b) (4)	22 Feb 2021 19:27:23

US3112389

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:14:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:17:45
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:36
User entered '22 Feb 2021'	Brenda Grande (b) (4) (b) (4)	22 Feb 2021 19:27:23

US3112389

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:14:10

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:17:45
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:36
User entered 'Contact Made (CONTACT MADE)'	Brenda Grande (b) (4) (b) (4)	22 Feb 2021 19:27:23

US3112389

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:14:10

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:17:45
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:36
User entered empty.	Brenda Grande (b) (4) (b) (4)	22 Feb 2021 19:27:23

US3112389

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:14:10

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:17:45
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:36
User entered 'Yes (Y)'	Brenda Grande (b) (4) (b) (4)	22 Feb 2021 19:27:17

US3112389

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:14:10

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:17:45
User entered 'I'	System	22 Feb 2021 19:27:17

US3112389

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:14:10

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:06:22
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Apr 2021 22:22:05

US3112389

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:14:10

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

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:06:22
User entered '25 Mar 2021'	(b) (4), (b) (6)	21 Apr 2021 22:22:05

US3112389

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:14:10

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

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:06:22
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	21 Apr 2021 22:22:05

US3112389

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:14:10

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT4'	System	21 Apr 2021 22:22:05

US3112389

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:14:10

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:06:22
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Apr 2021 22:22:56

US3112389

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:14:10

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:06:22
User entered '25 Mar 2021'	(b) (4), (b) (6)	21 Apr 2021 22:22:56

US3112389

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:14:10

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

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:06:22
User entered '14:31'	(b) (4), (b) (6)	21 Apr 2021 22:22:56

US3112389

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:14:10

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

Audit	User	Time (GMT)
User entered '25 Mar 2021 14:31'	System	21 Apr 2021 22:22:56

US3112389

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:14:10

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:06:22
User entered '98.3' F	(b) (4), (b) (6)	21 Apr 2021 22:22:56

US3112389

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:14:10

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:06:22
User entered 'Oral (Oral)'	(b) (4), (b) (6)	21 Apr 2021 22:22:56

US3112389

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:14:10

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:06:22
User entered empty.	(b) (4), (b) (6)	21 Apr 2021 22:22:56

US3112389

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:14:10

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:06:22
User entered '73'	(b) (4), (b) (6)	21 Apr 2021 22:22:56

US3112389

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:14:10

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	21 Apr 2021 22:22:56

US3112389

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:14:10

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

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:06:22
User entered '16'	(b) (4), (b) (6)	21 Apr 2021 22:22:56

US3112389

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:14:10

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	21 Apr 2021 22:22:56

US3112389

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:14:10

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:06:22
User entered '111'	(b) (4), (b) (6)	21 Apr 2021 22:22:56

US3112389

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:14:10

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	21 Apr 2021 22:22:56

US3112389

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:14:10

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:06:22
User entered '73'	(b) (4), (b) (6)	21 Apr 2021 22:22:56

US3112389

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:14:10

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	21 Apr 2021 22:22:56

US3112389

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:14:10

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:06:22
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Apr 2021 22:23:33

US3112389

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:14:10

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:06:22
User entered '25 Mar 2021'	(b) (4), (b) (6)	21 Apr 2021 22:23:33

US3112389

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:14:10

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:06:22
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Apr 2021 22:23:59

US3112389

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:14:10

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:06:22
User entered '25 Mar 2021'	(b) (4), (b) (6)	21 Apr 2021 22:23:59

US3112389

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:14:10

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:06:22
User entered '15:12'	(b) (4), (b) (6)	21 Apr 2021 22:23:59

US3112389

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:14:10

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '25 Mar 2021 15:12'	System	21 Apr 2021 22:23:59

US3112389

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:14:10

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:06:22
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Apr 2021 22:24:49

US3112389

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:14:10

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Apr 2021 22:24:49

US3112389

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:14:10

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:06:22
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Apr 2021 22:25:03

US3112389

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:14:10

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

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:06:22
User entered '21 Apr 2021'	(b) (4), (b) (6)	21 Apr 2021 22:25:03

US3112389

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:14:10

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:06:22
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	21 Apr 2021 22:25:03

US3112389

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:14:10

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:06:22
User entered empty.	(b) (4), (b) (6)	21 Apr 2021 22:25:03

US3112389

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:14:10

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:06:22
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Apr 2021 22:25:04

US3112389

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:14:10

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	21 Apr 2021 22:25:04

US3112389

Folder: Covid-19 Assessment 20 Jan 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:14:10

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered '20 Jan 2021'	Matthew Musikanth	22 Jan 2021 19:31:10
	(b) (4)	

US3112389

Folder: Covid-19 Assessment 20 Jan 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:14:10

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered '16:12'	Matthew Musikanth	22 Jan 2021 19:31:10
	(b) (4)	

US3112389

Folder: Covid-19 Assessment 20 Jan 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:14:10

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User entered '20 Jan 2021 16:12'	System	22 Jan 2021 19:31:10

US3112389

Folder: Covid-19 Assessment 20 Jan 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:14:10

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'Safety Call (Safety Call)'	Matthew Musikanth	22 Jan 2021 19:31:10
	(b) (4)	

US3112389

Folder: Covid-19 Assessment 20 Jan 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:14:10

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'Yes (Y)'	Matthew Musikanth	22 Jan 2021 19:31:10
	(b) (4)	

US3112389

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:14:10

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'Day 1 (Day 1)'	Matthew Musikanth	27 Jan 2021 18:03:32
	(b) (4)	

US3112389

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:14:10

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered '15 Jan 2021'	Matthew Musikanth	27 Jan 2021 18:03:32
	(b) (4)	

US3112389

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:14:10

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered '0'	Matthew Musikanth	27 Jan 2021 18:03:32
	(b) (4)	

US3112389

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:14:10

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered missing code ND - Not Done.	Matthew Musikanth	27 Jan 2021 18:03:32
	(b) (4)	

US3112389

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:14:10

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User entered '%'	System	27 Jan 2021 18:03:32

US3112389

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:14:10

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered missing code ND - Not Done.	Matthew Musikanth	27 Jan 2021 18:03:32
	(b) (4)	

US3112389

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:14:10

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'None (None)'	Matthew Musikanth	27 Jan 2021 18:03:32
	(b) (4)	

US3112389

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:14:10

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'None (None)'	Matthew Musikanth	27 Jan 2021 18:03:32
	(b) (4)	

US3112389

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:14:10

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'None (None)'	Matthew Musikanth	27 Jan 2021 18:03:32
	(b) (4)	

US3112389

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:14:10

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'None (None)'	Matthew Musikanth	27 Jan 2021 18:03:32
	(b) (4)	

US3112389

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:14:10

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'None (None)'	Matthew Musikanth	27 Jan 2021 18:03:32
	(b) (4)	

US3112389

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:14:10

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'None (None)'	Matthew Musikanth	27 Jan 2021 18:03:32
	(b) (4)	

US3112389

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:14:10

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'None (None)'	Matthew Musikanth	27 Jan 2021 18:03:32
	(b) (4)	

US3112389

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:14:10

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'None (None)'	Matthew Musikanth	27 Jan 2021 18:03:32
	(b) (4)	

US3112389

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:14:10

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'None (None)'	Matthew Musikanth	27 Jan 2021 18:03:32
	(b) (4)	

US3112389

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:14:10

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'None (None)'	Matthew Musikanth	27 Jan 2021 18:03:32
	(b) (4)	

US3112389

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:14:10

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'None (None)'	Matthew Musikanth	27 Jan 2021 18:03:32
	(b) (4)	

US3112389

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:14:10

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'Mild (Mild)'	Matthew Musikanth	27 Jan 2021 18:03:32
	(b) (4)	

US3112389

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:14:10

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'None (None)'	Matthew Musikanth	27 Jan 2021 18:03:32
	(b) (4)	

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Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:14:10

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'None (None)'	Matthew Musikanth	27 Jan 2021 18:03:32
	(b) (4)	

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Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:14:10

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'None (None)'	Matthew Musikanth	27 Jan 2021 18:03:32
	(b) (4)	

US3112389

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:14:10

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'None (None)'	Matthew Musikanth	27 Jan 2021 18:03:32
	(b) (4)	

US3112389

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:14:10

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'Day 2 (Day 2)'	Matthew Musikanth	27 Jan 2021 18:21:58
	(b) (4)	

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Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:14:10

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered '16 Jan 2021'	Matthew Musikanth	27 Jan 2021 18:21:58
	(b) (4)	

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Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:14:10

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered '0'	Matthew Musikanth	27 Jan 2021 18:21:58
	(b) (4)	

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Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:14:10

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered missing code ND - Not Done.	Matthew Musikanth	27 Jan 2021 18:21:58
	(b) (4)	

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Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (2)

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[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User entered '%'	System	27 Jan 2021 18:21:58

US3112389

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:14:10

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered missing code ND - Not Done.	Matthew Musikanth	27 Jan 2021 18:21:58
	(b) (4)	

US3112389

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:14:10

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'None (None)'	Matthew Musikanth	27 Jan 2021 18:21:58
	(b) (4)	

US3112389

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (2)

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[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'None (None)'	Matthew Musikanth	27 Jan 2021 18:21:58
	(b) (4)	

US3112389

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (2)

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[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'None (None)'	Matthew Musikanth	27 Jan 2021 18:21:58
	(b) (4)	

US3112389

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:14:10

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'None (None)'	Matthew Musikanth	27 Jan 2021 18:21:58
	(b) (4)	

US3112389

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:14:10

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'None (None)'	Matthew Musikanth	27 Jan 2021 18:21:58
	(b) (4)	

US3112389

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:14:10

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'Mild (Mild)'	Matthew Musikanth	27 Jan 2021 18:21:58
	(b) (4)	

US3112389

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:14:10

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'Mild (Mild)'	Matthew Musikanth	27 Jan 2021 18:21:58
	(b) (4)	

US3112389

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:14:10

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'Mild (Mild)'	Matthew Musikanth	27 Jan 2021 18:21:58
	(b) (4)	

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Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:14:10

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'None (None)'	Matthew Musikanth	27 Jan 2021 18:21:58
	(b) (4)	

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Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:14:10

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'None (None)'	Matthew Musikanth	27 Jan 2021 18:21:58
	(b) (4)	

US3112389

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:14:10

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'None (None)'	Matthew Musikanth	27 Jan 2021 18:21:58
	(b) (4)	

US3112389

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:14:10

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'Mild (Mild)'	Matthew Musikanth	27 Jan 2021 18:21:58
	(b) (4)	

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Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:14:10

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'None (None)'	Matthew Musikanth	27 Jan 2021 18:21:58
	(b) (4)	

US3112389

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:14:10

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'None (None)'	Matthew Musikanth	27 Jan 2021 18:21:58
	(b) (4)	

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Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:14:10

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'None (None)'	Matthew Musikanth	27 Jan 2021 18:21:58
	(b) (4)	

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Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:14:10

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'None (None)'	Matthew Musikanth	27 Jan 2021 18:21:58
	(b) (4)	

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Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (3)

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'Day 3 (Day 3)'	Matthew Musikanth	27 Jan 2021 18:21:58
	(b) (4)	

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Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:14:10

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered '17 Jan 2021'	Matthew Musikanth	27 Jan 2021 18:21:58
	(b) (4)	

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Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:14:10

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered '0'	Matthew Musikanth	27 Jan 2021 18:21:58
	(b) (4)	

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Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:14:10

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered missing code ND - Not Done.	Matthew Musikanth	27 Jan 2021 18:21:58
	(b) (4)	

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Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:14:10

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User entered '%'	System	27 Jan 2021 18:21:58

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[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered missing code ND - Not Done.	Matthew Musikanth	27 Jan 2021 18:21:58
	(b) (4)	

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Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:14:10

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'None (None)'	Matthew Musikanth	27 Jan 2021 18:21:58
	(b) (4)	

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Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:14:10

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'None (None)'	Matthew Musikanth	27 Jan 2021 18:21:58
	(b) (4)	

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Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:14:10

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'None (None)'	Matthew Musikanth	27 Jan 2021 18:21:58
	(b) (4)	

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Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:14:10

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'None (None)'	Matthew Musikanth	27 Jan 2021 18:21:58
	(b) (4)	

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Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:14:10

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'Mild (Mild)'	Matthew Musikanth	27 Jan 2021 18:21:58
	(b) (4)	

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Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:14:10

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'Mild (Mild)'	Matthew Musikanth	27 Jan 2021 18:21:58
	(b) (4)	

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Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:14:10

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'Mild (Mild)'	Matthew Musikanth	27 Jan 2021 18:21:58
	(b) (4)	

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Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:14:10

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'Mild (Mild)'	Matthew Musikanth	27 Jan 2021 18:21:58
	(b) (4)	

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Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:14:10

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'None (None)'	Matthew Musikanth	27 Jan 2021 18:21:58
	(b) (4)	

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Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:14:10

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'None (None)'	Matthew Musikanth	27 Jan 2021 18:21:58
	(b) (4)	

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Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:14:10

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'None (None)'	Matthew Musikanth	27 Jan 2021 18:21:58
	(b) (4)	

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Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:14:10

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'Mild (Mild)'	Matthew Musikanth	27 Jan 2021 18:21:58
	(b) (4)	

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Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:14:10

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'None (None)'	Matthew Musikanth	27 Jan 2021 18:21:58
	(b) (4)	

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Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:14:10

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'None (None)'	Matthew Musikanth	27 Jan 2021 18:21:58
	(b) (4)	

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Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:14:10

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'None (None)'	Matthew Musikanth	27 Jan 2021 18:21:58
	(b) (4)	

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Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:14:10

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'None (None)'	Matthew Musikanth	27 Jan 2021 18:21:58
	(b) (4)	

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Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:14:10

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'Day 4 (Day 4)'	Matthew Musikanth	27 Jan 2021 18:21:58
	(b) (4)	

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Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:14:10

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered '18 Jan 2021'	Matthew Musikanth	27 Jan 2021 18:21:58
	(b) (4)	

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Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:14:10

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered '0'	Matthew Musikanth	27 Jan 2021 18:21:58
	(b) (4)	

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Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:14:10

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered missing code ND - Not Done.	Matthew Musikanth	27 Jan 2021 18:21:58
	(b) (4)	

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Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:14:10

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User entered '%'	System	27 Jan 2021 18:21:58

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Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:14:10

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered missing code ND - Not Done.	Matthew Musikanth	27 Jan 2021 18:21:58
	(b) (4)	

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Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:14:10

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'None (None)'	Matthew Musikanth	27 Jan 2021 18:21:58
	(b) (4)	

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Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:14:10

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'None (None)'	Matthew Musikanth	27 Jan 2021 18:21:58
	(b) (4)	

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Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:14:10

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'None (None)'	Matthew Musikanth	27 Jan 2021 18:21:58
	(b) (4)	

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Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:14:10

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'None (None)'	Matthew Musikanth	27 Jan 2021 18:21:58
	(b) (4)	

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Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:14:10

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'Mild (Mild)'	Matthew Musikanth	27 Jan 2021 18:21:58
	(b) (4)	

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Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:14:10

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'None (None)'	Matthew Musikanth	27 Jan 2021 18:21:58
	(b) (4)	

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Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:14:10

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'None (None)'	Matthew Musikanth	27 Jan 2021 18:21:58
	(b) (4)	

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Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:14:10

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'Mild (Mild)'	Matthew Musikanth	27 Jan 2021 18:21:58
	(b) (4)	

US3112389

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:14:10

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'None (None)'	Matthew Musikanth	27 Jan 2021 18:21:58
	(b) (4)	

US3112389

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:14:10

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'None (None)'	Matthew Musikanth	27 Jan 2021 18:21:58
	(b) (4)	

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Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:14:10

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'None (None)'	Matthew Musikanth	27 Jan 2021 18:21:58
	(b) (4)	

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Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:14:10

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'Mild (Mild)'	Matthew Musikanth	27 Jan 2021 18:21:58
	(b) (4)	

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Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:14:10

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'None (None)'	Matthew Musikanth	27 Jan 2021 18:21:58
	(b) (4)	

US3112389

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:14:10

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'None (None)'	Matthew Musikanth	27 Jan 2021 18:21:58
	(b) (4)	

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Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:14:10

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'None (None)'	Matthew Musikanth	27 Jan 2021 18:21:58
	(b) (4)	

US3112389

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:14:10

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'Mild (Mild)'	Matthew Musikanth	27 Jan 2021 18:21:58
	(b) (4)	

US3112389

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:14:10

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'Day 5 (Day 5)'	Matthew Musikanth	27 Jan 2021 18:21:58
	(b) (4)	

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Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:14:10

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered '19 Jan 2021'	Matthew Musikanth	27 Jan 2021 18:21:58
	(b) (4)	

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Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:14:10

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered '0'	Matthew Musikanth	27 Jan 2021 18:21:58
	(b) (4)	

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Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:14:10

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered missing code ND - Not Done.	Matthew Musikanth	27 Jan 2021 18:21:58
	(b) (4)	

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Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:14:10

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User entered '%'	System	27 Jan 2021 18:21:58

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Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:14:10

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered missing code ND - Not Done.	Matthew Musikanth	27 Jan 2021 18:21:58
	(b) (4)	

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Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:14:10

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'None (None)'	Matthew Musikanth	27 Jan 2021 18:21:58
	(b) (4)	

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Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:14:10

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'None (None)'	Matthew Musikanth	27 Jan 2021 18:21:58
	(b) (4)	

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Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:14:10

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'None (None)'	Matthew Musikanth	27 Jan 2021 18:21:58
	(b) (4)	

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Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:14:10

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'None (None)'	Matthew Musikanth	27 Jan 2021 18:21:58
	(b) (4)	

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Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:14:10

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'Mild (Mild)'	Matthew Musikanth	27 Jan 2021 18:21:58
	(b) (4)	

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Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:14:10

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'None (None)'	Matthew Musikanth	27 Jan 2021 18:21:58
	(b) (4)	

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Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:14:10

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'None (None)'	Matthew Musikanth	27 Jan 2021 18:21:58
	(b) (4)	

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Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:14:10

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'Mild (Mild)'	Matthew Musikanth	27 Jan 2021 18:21:58
	(b) (4)	

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Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:14:10

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'None (None)'	Matthew Musikanth	27 Jan 2021 18:21:58
	(b) (4)	

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Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:14:10

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'None (None)'	Matthew Musikanth	27 Jan 2021 18:21:58
	(b) (4)	

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Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:14:10

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'None (None)'	Matthew Musikanth	27 Jan 2021 18:21:58
	(b) (4)	

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Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:14:10

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'Mild (Mild)'	Matthew Musikanth	27 Jan 2021 18:21:58
	(b) (4)	

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Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:14:10

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'None (None)'	Matthew Musikanth	27 Jan 2021 18:21:58
	(b) (4)	

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Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:14:10

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'None (None)'	Matthew Musikanth	27 Jan 2021 18:21:58
	(b) (4)	

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Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:14:10

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'None (None)'	Matthew Musikanth	27 Jan 2021 18:21:58
	(b) (4)	

US3112389

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:14:10

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'Mild (Mild)'	Matthew Musikanth	27 Jan 2021 18:21:58
	(b) (4)	

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Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:14:10

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'Day 6 (Day 6)'	Matthew Musikanth	27 Jan 2021 18:21:58
	(b) (4)	

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Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:14:10

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered '20 Jan 2021'	Matthew Musikanth	27 Jan 2021 18:21:58
	(b) (4)	

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Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:14:10

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered '0'	Matthew Musikanth	27 Jan 2021 18:21:58
	(b) (4)	

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Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:14:10

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered missing code ND - Not Done.	Matthew Musikanth	27 Jan 2021 18:21:58
	(b) (4)	

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Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:14:10

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User entered '%'	System	27 Jan 2021 18:21:58

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Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:14:10

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered missing code ND - Not Done.	Matthew Musikanth	27 Jan 2021 18:21:58
	(b) (4)	

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Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:14:10

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'None (None)'	Matthew Musikanth	27 Jan 2021 18:21:58
	(b) (4)	

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Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:14:10

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'None (None)'	Matthew Musikanth	27 Jan 2021 18:21:58
	(b) (4)	

US3112389

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:14:10

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'None (None)'	Matthew Musikanth	27 Jan 2021 18:21:58
	(b) (4)	

US3112389

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:14:10

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'None (None)'	Matthew Musikanth	27 Jan 2021 18:21:58
	(b) (4)	

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Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:14:10

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'None (None)'	Matthew Musikanth	27 Jan 2021 18:21:58
	(b) (4)	

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Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:14:10

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'None (None)'	Matthew Musikanth	27 Jan 2021 18:21:58
	(b) (4)	

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Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:14:10

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'None (None)'	Matthew Musikanth	27 Jan 2021 18:21:58
	(b) (4)	

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Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:14:10

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'Mild (Mild)'	Matthew Musikanth	27 Jan 2021 18:21:58
	(b) (4)	

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Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:14:10

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'None (None)'	Matthew Musikanth	27 Jan 2021 18:21:58
	(b) (4)	

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Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:14:10

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'None (None)'	Matthew Musikanth	27 Jan 2021 18:21:58
	(b) (4)	

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Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:14:10

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'None (None)'	Matthew Musikanth	27 Jan 2021 18:21:58
	(b) (4)	

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[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'Mild (Mild)'	Matthew Musikanth	27 Jan 2021 18:21:58
	(b) (4)	

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Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (6)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'None (None)'	Matthew Musikanth	27 Jan 2021 18:21:58
	(b) (4)	

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Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:14:10

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'None (None)'	Matthew Musikanth	27 Jan 2021 18:21:58
	(b) (4)	

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Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:14:10

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'None (None)'	Matthew Musikanth	27 Jan 2021 18:21:58
	(b) (4)	

US3112389

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:14:10

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'Mild (Mild)'	Matthew Musikanth	27 Jan 2021 18:21:58
	(b) (4)	

US3112389

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:14:10

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'Day 7 (Day 7)'	Matthew Musikanth	27 Jan 2021 18:21:58
	(b) (4)	

US3112389

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:14:10

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered '21 Jan 2021'	Matthew Musikanth	27 Jan 2021 18:21:58
	(b) (4)	

US3112389

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:14:10

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered '0'	Matthew Musikanth	27 Jan 2021 18:21:58
	(b) (4)	

US3112389

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:14:10

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered '97'	Matthew Musikanth	27 Jan 2021 18:21:58
	(b) (4)	

US3112389

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:14:10

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User entered '%'	System	27 Jan 2021 18:21:58

US3112389

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:14:10

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered '97.7' F	Matthew Musikanth	27 Jan 2021 18:21:58
	(b) (4)	

US3112389

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:14:10

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'None (None)'	Matthew Musikanth	27 Jan 2021 18:21:58
	(b) (4)	

US3112389

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:14:10

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'None (None)'	Matthew Musikanth	27 Jan 2021 18:21:58
	(b) (4)	

US3112389

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:14:10

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'None (None)'	Matthew Musikanth	27 Jan 2021 18:21:58
	(b) (4)	

US3112389

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:14:10

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'None (None)'	Matthew Musikanth	27 Jan 2021 18:21:58
	(b) (4)	

US3112389

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:14:10

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'Mild (Mild)'	Matthew Musikanth	27 Jan 2021 18:21:58
	(b) (4)	

US3112389

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:14:10

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'None (None)'	Matthew Musikanth	27 Jan 2021 18:21:58
	(b) (4)	

US3112389

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:14:10

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'None (None)'	Matthew Musikanth	27 Jan 2021 18:21:58
	(b) (4)	

US3112389

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:14:10

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'None (None)'	Matthew Musikanth	27 Jan 2021 18:21:58
	(b) (4)	

US3112389

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:14:10

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'None (None)'	Matthew Musikanth	27 Jan 2021 18:21:58
	(b) (4)	

US3112389

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:14:10

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'None (None)'	Matthew Musikanth	27 Jan 2021 18:21:58
	(b) (4)	

US3112389

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:14:10

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'None (None)'	Matthew Musikanth	27 Jan 2021 18:21:58
	(b) (4)	

US3112389

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:14:10

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'Mild (Mild)'	Matthew Musikanth	27 Jan 2021 18:21:58
	(b) (4)	

US3112389

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:14:10

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'None (None)'	Matthew Musikanth	27 Jan 2021 18:21:58
	(b) (4)	

US3112389

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:14:10

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'None (None)'	Matthew Musikanth	27 Jan 2021 18:21:58
	(b) (4)	

US3112389

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:14:10

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'None (None)'	Matthew Musikanth	27 Jan 2021 18:21:58
	(b) (4)	

US3112389

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:14:10

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'None (None)'	Matthew Musikanth	27 Jan 2021 18:21:58
	(b) (4)	

US3112389

Folder: Covid-19 Assessment 20 Jan 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:14:10

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
User entered '21 Jan 2021' reason for change: Data Entry Error	Brenda Grande (b) (4) (b) (4)	10 Feb 2021 18:20:23
User entered '20 Jan 2021'	Matthew Musikanth (b) (4)	22 Jan 2021 19:32:23

US3112389

Folder: Covid-19 Assessment 20 Jan 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:14:10

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'Yes (Y)'	Matthew Musikanth	22 Jan 2021 19:32:23
	(b) (4)	

US3112389

Folder: Covid-19 Assessment 20 Jan 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:14:10

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'No (N)'	Matthew Musikanth	22 Jan 2021 19:32:23
	(b) (4)	

US3112389

Folder: Covid-19 Assessment 20 Jan 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:14:10

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
User closed query 'Per GCL Lab Reconciliation: Swab: Sample Collection date is recorded as 18JAN2021 under Covid-19 Assessment in EDC, however same is missing in PPD central lab. Please reconcile the data and amend GCL or Preclarus as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 07:06:47
Query 'Per GCL Lab Reconciliation: Swab: Sample Collection date is recorded as 18JAN2021 under Covid-19 Assessment in EDC, however same is missing in PPD central lab. Please reconcile the data and amend GCL or Preclarus as appropriate. Thank you.' answered with ' edc updated ' (Site from DM).	Brenda Grande (b) (4) (b) (4)	10 Feb 2021 18:20:37
User entered '21 Jan 2021' reason for change: Data Entry Error	Brenda Grande (b) (4) (b) (4)	10 Feb 2021 18:20:23
User opened query 'Per GCL Lab Reconciliation: Swab: Sample Collection date is recorded as 18JAN2021 under Covid-19 Assessment in EDC, however same is missing in PPD central lab. Please reconcile the data and amend GCL or Preclarus as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	05 Feb 2021 10:09:53
User entered '18 Jan 2021'	Matthew Musikanth (b) (4)	22 Jan 2021 19:32:23

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Folder: Covid-19 Assessment 20 Jan 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:14:10

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Matthew Musikanth (b) (4)	22 Jan 2021 19:32:23

US3112389

Folder: Covid-19 Assessment 20 Jan 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:14:10

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered empty.	Matthew Musikanth	22 Jan 2021 19:32:23
	(b) (4)	

US3112389

Folder: Covid-19 Assessment 20 Jan 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:14:10

[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)	30 Apr 2021 12:50:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'Yes (Y)'	Matthew Musikanth	22 Jan 2021 19:32:23
	(b) (4)	

US3112389

Folder: Covid-19 Assessment 20 Jan 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:14:10

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'County of San Diego Testing Site'	Matthew Musikanth	22 Jan 2021 19:32:23
	(b) (4)	

US3112389

Folder: Covid-19 Assessment 20 Jan 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:14:10

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'Yes (Y)'	Matthew Musikanth	22 Jan 2021 19:32:23
	(b) (4)	

US3112389

Folder: Covid-19 Assessment 20 Jan 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:14:10

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:50:18
User entered '0'	System	22 Jan 2021 19:32:23

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Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 15:14:10

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:25:39
User accepted default value 'Day 3 (Day 3)'	Matthew Musikanth (b) (4)	27 Jan 2021 18:24:29

US3112389

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 15:14:10

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:25:39
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'NA (COVID-19 Negative) (NA)'	Matthew Musikanth	27 Jan 2021 18:24:29
	(b) (4)	

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Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 15:14:10

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:25:39
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered empty.	Matthew Musikanth	27 Jan 2021 18:24:29
	(b) (4)	

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Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 15:14:10

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:25:39
User accepted default value 'Day 5 (Day 5)'	Matthew Musikanth (b) (4)	27 Jan 2021 18:24:29

US3112389

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 15:14:10

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:25:39
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'NA (COVID-19 Negative) (NA)'	Matthew Musikanth	27 Jan 2021 18:24:29
	(b) (4)	

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Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 15:14:10

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:25:39
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered empty.	Matthew Musikanth	27 Jan 2021 18:24:29
	(b) (4)	

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Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 15:14:10

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:25:39
User accepted default value 'Day 7 (Day 7)'	Matthew Musikanth (b) (4)	27 Jan 2021 18:24:29

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Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 15:14:10

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:25:39
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'NA (COVID-19 Negative) (NA)'	Matthew Musikanth	27 Jan 2021 18:24:29
	(b) (4)	

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Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 15:14:10

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:25:39
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered empty.	Matthew Musikanth	27 Jan 2021 18:24:29
	(b) (4)	

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Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 15:14:10

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:25:39
User accepted default value 'Day 9 (Day 9)'	Matthew Musikanth (b) (4)	27 Jan 2021 18:24:29

US3112389

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 15:14:10

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:25:39
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'NA (COVID-19 Negative) (NA)'	Matthew Musikanth	27 Jan 2021 18:24:29
	(b) (4)	

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Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 15:14:10

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:25:39
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered empty.	Matthew Musikanth	27 Jan 2021 18:24:29
	(b) (4)	

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Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 15:14:10

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:25:39
User accepted default value 'Day 14 (Day 14)'	Matthew Musikanth (b) (4)	27 Jan 2021 18:24:29

US3112389

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 15:14:10

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:25:39
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'NA (COVID-19 Negative) (NA)'	Matthew Musikanth	27 Jan 2021 18:24:29
	(b) (4)	

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Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 15:14:10

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:25:39
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered empty.	Matthew Musikanth	27 Jan 2021 18:24:29
	(b) (4)	

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Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 15:14:10

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:25:39
User accepted default value 'Day 21 (Day 21)'	Matthew Musikanth (b) (4)	27 Jan 2021 18:24:29

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Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 15:14:10

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:25:39
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'NA (COVID-19 Negative) (NA)'	Matthew Musikanth	27 Jan 2021 18:24:29
	(b) (4)	

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Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 15:14:10

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:25:39
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered empty.	Matthew Musikanth	27 Jan 2021 18:24:29
	(b) (4)	

US3112389

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 15:14:10

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:25:39
User accepted default value 'Day 28 (Day 28)'	Matthew Musikanth (b) (4)	27 Jan 2021 18:24:29

US3112389

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 15:14:10

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:25:39
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'NA (COVID-19 Negative) (NA)'	Matthew Musikanth	27 Jan 2021 18:24:29
	(b) (4)	

US3112389

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 15:14:10

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:25:39
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered empty.	Matthew Musikanth	27 Jan 2021 18:24:29
	(b) (4)	

US3112389

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:14:10

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:25:39
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'Yes (Y)'	Matthew Musikanth	27 Jan 2021 18:22:36
	(b) (4)	

US3112389

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:14:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:25:39
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered '21 Jan 2021'	Matthew Musikanth	27 Jan 2021 18:22:36
	(b) (4)	

US3112389

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:14:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:25:39
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'Clinic (Clinic)'	Matthew Musikanth	27 Jan 2021 18:22:36
	(b) (4)	

US3112389

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:14:10

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:25:39
User entered 'SICKD1'	System	27 Jan 2021 18:22:36

US3112389

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:14:10

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:25:39
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'Yes (Y)'	Matthew Musikanth	27 Jan 2021 18:23:03
	(b) (4)	

US3112389

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:14:10

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:25:39
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered '21 Jan 2021'	Matthew Musikanth	27 Jan 2021 18:23:03
	(b) (4)	

US3112389

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:14:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:25:39
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered '14:17'	Matthew Musikanth	27 Jan 2021 18:23:03
	(b) (4)	

US3112389

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:14:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:25:39
User entered '21 Jan 2021 14:17'	System	27 Jan 2021 18:23:03

US3112389

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:14:10

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:25:39
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered missing code ND - Not Done.	Matthew Musikanth	27 Jan 2021 18:23:03
	(b) (4)	
DataPoint set to visible.	System	27 Jan 2021 18:22:36

US3112389

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:14:10

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:25:39
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered missing code ND - Not Done.	Matthew Musikanth	27 Jan 2021 18:23:03
	(b) (4)	
DataPoint set to visible.	System	27 Jan 2021 18:22:36

US3112389

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:14:10

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:25:39
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered '97.7' F	Matthew Musikanth	27 Jan 2021 18:23:03
	(b) (4)	

US3112389

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:14:10

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:25:39
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'Oral (Oral)'	Matthew Musikanth	27 Jan 2021 18:23:03
	(b) (4)	

US3112389

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:14:10

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:25:39
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered empty.	Matthew Musikanth	27 Jan 2021 18:23:03
	(b) (4)	

US3112389

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:14:10

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:25:39
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered '76'	Matthew Musikanth	27 Jan 2021 18:23:03
	(b) (4)	

US3112389

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:14:10

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:25:39
User entered 'bpm'	System	27 Jan 2021 18:23:03

US3112389

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:14:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:25:39
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered '16'	Matthew Musikanth	27 Jan 2021 18:23:03
	(b) (4)	

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Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:14:10

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:25:39
User entered 'breaths/min'	System	27 Jan 2021 18:23:03

US3112389

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:14:10

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:25:39
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered '112'	Matthew Musikanth	27 Jan 2021 18:23:03
	(b) (4)	

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Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:14:10

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:25:39
User entered 'mmHg'	System	27 Jan 2021 18:23:03

US3112389

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:14:10

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:25:39
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered '76'	Matthew Musikanth	27 Jan 2021 18:23:03
	(b) (4)	

US3112389

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:14:10

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:25:39
User entered 'mmHg'	System	27 Jan 2021 18:23:03

US3112389

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:14:10

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:25:39

US3112389

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:14:10

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:25:39

US3112389

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:14:10

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:25:39
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'Yes (Y)'	Matthew Musikanth	27 Jan 2021 18:23:13
	(b) (4)	

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Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:14:10

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:25:39
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered '21 Jan 2021'	Matthew Musikanth	27 Jan 2021 18:23:13
	(b) (4)	

US3112389

Folder: Illness Visit Day 1 (1)

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

Generated On: 09 Jun 2021 15:14:10

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:25:39
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'Yes (Y)'	Matthew Musikanth	27 Jan 2021 18:23:22
	(b) (4)	

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Folder: Illness Visit Day 1 (1)

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

Generated On: 09 Jun 2021 15:14:10

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:25:39
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered '21 Jan 2021'	Matthew Musikanth	27 Jan 2021 18:23:22
	(b) (4)	

US3112389

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

Form: Visit Date

Generated On: 09 Jun 2021 15:14:10

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:55
User closed query ' Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 04MAR2021 is reported under visit 4 in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under correct visit in EDC. ' (Site from DM). Query '	(b) (4), (b) (6)	21 Apr 2021 04:39:22
Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 04MAR2021 is reported under visit 4 in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under correct visit in EDC. ' answered with 'Please note that patient was not seen on 04Mar2021, last visit is 25Mar2021' (Site from DM).	Matthew Musikanth (b) (4)	16 Apr 2021 16:56:12
User opened query ' Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 04MAR2021 is reported under visit 4 in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under correct visit in EDC. ' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 10:47:45
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 25MAR2021 is reported under visit 4 in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under Visit 4 on Immunogenicity Assessment page.' canceled (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 10:47:41
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 25MAR2021 is reported under visit 4 in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under Visit 4 on Immunogenicity Assessment page.' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 10:40:07

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EAB) (1725)

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

Form: Visit Date

Generated On: 09 Jun 2021 15:14:10

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
User entered 'Yes (Y)'	Brenda Grande (b) (4) (b) (4)	08 Jan 2021 00:30:31

US3112389

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

Form: Visit Date

Generated On: 09 Jun 2021 15:14:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:55
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
User entered '7 Jan 2021'	Brenda Grande (b) (4) (b) (4)	08 Jan 2021 00:30:31

US3112389

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

Form: Visit Date

Generated On: 09 Jun 2021 15:14:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:55
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
User entered 'Clinic (Clinic)'	Brenda Grande (b) (4) (b) (4)	08 Jan 2021 00:30:31

US3112389

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

Form: Visit Date

Generated On: 09 Jun 2021 15:14:10

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:55
User entered 'UNBLND_DECIDE'	System	08 Jan 2021 00:30:31

US3112389

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

Form: Unblinding

Generated On: 09 Jun 2021 15:14:10

Date of updated informed consent (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:55
User closed query 'Per sponsor review, This field relates to Amendment 6. The Amendment 6 consent form was not available until 29DEC2020. Please review and update field to the date the subject signed the Amendment 6 or later consent form. If the subject was unblinded and discontinued under Amendment 5, please tick the box below indicating that the consent field is N/A and the subject was unblinded and discontinued under Amendment 5.' (Site from DM). User signature succeeded.	(b) (4), (b) (6) Todd Simmons (b) (4) (b) (4)	19 Apr 2021 11:39:20 09 Apr 2021 00:13:43
Query 'Per sponsor review, This field relates to Amendment 6. The Amendment 6 consent form was not available until 29DEC2020. Please review and update field to the date the subject signed the Amendment 6 or later consent form. If the subject was unblinded and discontinued under Amendment 5, please tick the box below indicating that the consent field is N/A and the subject was unblinded and discontinued under Amendment 5.' answered with 'updated' (Site from DM). Signature has been broken.	Brenda Grande (b) (4) (b) (4) Brenda Grande (b) (4) (b) (4)	07 Apr 2021 18:09:10 07 Apr 2021 18:08:55 07 Apr 2021 18:08:55
User entered '7 Jan 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Apr 2021 17:40:38
User opened query 'Per sponsor review, This field relates to Amendment 6. The Amendment 6 consent form was not available until 29DEC2020. Please review and update field to the date the subject signed the Amendment 6 or later consent form. If the subject was unblinded and discontinued under Amendment 5, please tick the box below indicating that the consent field is N/A and the subject was unblinded and discontinued under Amendment 5.' (Site from DM). User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
User entered '24 Dec 2020'	Brenda Grande (b) (4) (b) (4)	08 Jan 2021 00:31:01

US3112389

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

Form: Unblinding

Generated On: 09 Jun 2021 15:14:10

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:55
User signature succeeded.	Todd Simmons (b) (4)	09 Apr 2021 00:13:43
	(b) (4)	
User entered '0'	Brenda Grande (b) (4)	07 Apr 2021 18:08:55
	(b) (4)	
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 14:04:29

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

Form: Unblinding

Generated On: 09 Jun 2021 15:14:10

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:55
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
User entered 'Yes (Y)'	Brenda Grande (b) (4) (b) (4)	08 Jan 2021 00:31:01

US3112389

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

Form: Unblinding

Generated On: 09 Jun 2021 15:14:10

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:55
User signature succeeded.	Todd Simmons (b) (4)	09 Apr 2021 00:13:43
	(b) (4)	
User entered 'Amendment 6 or later (Amendment 6 or later)'	Brenda Grande (b) (4)	07 Apr 2021 18:08:55
	(b) (4)	
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 14:04:29

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

Form: Unblinding

Generated On: 09 Jun 2021 15:14:10

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:55
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered '7 Jan 2021'	Brenda Grande (b) (4)	08 Jan 2021 00:31:01
	(b) (4)	

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

Form: Unblinding

Generated On: 09 Jun 2021 15:14:10

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:55
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
User entered 'mRNA-1273 (mRNA-1273)'	Brenda Grande (b) (4) (b) (4)	08 Jan 2021 00:31:01

US3112389

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

Form: Unblinding

Generated On: 09 Jun 2021 15:14:10

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:55
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	System	20 Jan 2021 08:31:38
User entered 'mRNA-1273 (mRNA-1273)'	Brenda Grande (b) (4)	08 Jan 2021 00:31:01
	(b) (4)	

US3112389

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

Form: Unblinding

Generated On: 09 Jun 2021 15:14:10

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:55
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	System	20 Jan 2021 08:31:38
User entered 'mRNA-1273 (mRNA-1273)'	Brenda Grande (b) (4)	08 Jan 2021 00:31:01
	(b) (4)	

US3112389

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

Form: Unblinding

Generated On: 09 Jun 2021 15:14:10

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:55
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
User entered 'No (N)'	Brenda Grande (b) (4) (b) (4)	08 Jan 2021 00:31:01

US3112389

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

Form: Unblinding

Generated On: 09 Jun 2021 15:14:10

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:55
User entered empty.	System	08 Jan 2021 00:31:01

US3112389

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

Form: Unblinding

Generated On: 09 Jun 2021 15:14:10

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:55
User entered empty.	System	08 Jan 2021 00:31:01

US3112389

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:14:10

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:55
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
User entered 'Yes (Y)'	Brenda Grande (b) (4) (b) (4)	08 Jan 2021 00:31:21

US3112389

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:14:10

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:55
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
User entered '7 Jan 2021'	Brenda Grande (b) (4) (b) (4)	08 Jan 2021 00:31:21

US3112389

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:14:10

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:55
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered '11:47'	Brenda Grande (b) (4)	08 Jan 2021 00:31:21
	(b) (4)	

US3112389

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:14:10

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:55
User entered '7 Jan 2021 11:47'	System	08 Jan 2021 00:31:21

US3112389

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:14:10

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:55
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
User entered 'Yes (Y)'	Brenda Grande (b) (4) (b) (4)	08 Jan 2021 00:31:34

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:14:10

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:55
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
User entered '7 Jan 2021'	Brenda Grande (b) (4) (b) (4)	08 Jan 2021 00:31:34

US3112389

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:14:10

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:55
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered '11:35'	Brenda Grande (b) (4)	08 Jan 2021 00:31:34
	(b) (4)	

US3112389

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:14:10

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:38:55
User entered '7 Jan 2021 11:35'	System	08 Jan 2021 00:31:34

US3112389

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 15:14:10

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:45:06
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:25:53
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:34:25
	(b) (4)	
User entered 'Yes (Y)'	Matthew Musikanth	19 Nov 2020 17:07:50
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:14:10

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:11:39

US3112389

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:14:10

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:11:39
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:34:25
	(b) (4)	
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Urinary tract infections, PT: Urinary tract infection, LLT: UTI - version MedDRA\\23.0.	Coder Import (b) (4)	19 Nov 2020 17:10:00
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	19 Nov 2020 17:10:00
	(b) (4)	
Data point term sent to Coder	System	19 Nov 2020 17:08:51
User entered 'UTI'	Matthew Musikanth	19 Nov 2020 17:08:26
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:14:10

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:11:39
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:34:25
	(b) (4)	
User entered 'Yes (Y)'	Matthew Musikanth	19 Nov 2020 17:08:26
	(b) (4)	

US3112389

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:14:10

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:11:39
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:34:25
	(b) (4)	
User entered 'No (N)'	Matthew Musikanth	19 Nov 2020 17:08:26
	(b) (4)	

US3112389

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:14:10

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:11:39
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:34:25
	(b) (4)	
User entered 'No (N)'	Matthew Musikanth	19 Nov 2020 17:08:26
	(b) (4)	

US3112389

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:14:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:11:39
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:34:25
	(b) (4)	
User entered '10 Nov 2020'	Matthew Musikanth	19 Nov 2020 17:08:26
	(b) (4)	

US3112389

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:14:10

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:11:39
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:34:25
	(b) (4)	
User entered empty.	Matthew Musikanth	19 Nov 2020 17:08:26
	(b) (4)	

US3112389

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:14:10

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:11:39
User entered empty.	System	19 Nov 2020 17:08:26

US3112389

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:14:10

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:11:39
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:34:25
	(b) (4)	
User entered 'No (N)'	Matthew Musikanth	19 Nov 2020 17:08:26
	(b) (4)	

US3112389

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:14:10

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:11:39
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:34:25
	(b) (4)	
User entered '15 Nov 2020'	Matthew Musikanth	19 Nov 2020 17:08:26
	(b) (4)	

US3112389

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:14:10

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:11:39
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:34:25
	(b) (4)	
User entered empty.	Matthew Musikanth	19 Nov 2020 17:08:26
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:14:10

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:11:39
User entered empty.	System	19 Nov 2020 17:08:26

US3112389

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:14:10

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:11:39
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:34:25
	(b) (4)	
User entered 'Grade 1/Mild (Grade 1/Mild)'	Matthew Musikanth	19 Nov 2020 17:08:26
	(b) (4)	

US3112389

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:14:10

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:11:39
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:34:25
	(b) (4)	
User entered 'No (N)'	Matthew Musikanth	19 Nov 2020 17:08:26
	(b) (4)	

US3112389

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:14:10

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:11:39
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:34:25
	(b) (4)	
User entered '0'	Matthew Musikanth	19 Nov 2020 17:08:26
	(b) (4)	

US3112389

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:14:10

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:11:39
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:34:25
	(b) (4)	
User entered '0'	Matthew Musikanth	19 Nov 2020 17:08:26
	(b) (4)	

US3112389

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:14:10

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:11:39
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:34:25
	(b) (4)	
User entered '0'	Matthew Musikanth	19 Nov 2020 17:08:26
	(b) (4)	

US3112389

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:14:10

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:11:39
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:34:25
	(b) (4)	
User entered empty.	Matthew Musikanth	19 Nov 2020 17:08:26
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:14:10

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:11:39
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:34:25
	(b) (4)	
User entered empty.	Matthew Musikanth	19 Nov 2020 17:08:26
	(b) (4)	

US3112389

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:14:10

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:11:39
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:34:25
	(b) (4)	
User entered empty.	Matthew Musikanth	19 Nov 2020 17:08:26
	(b) (4)	

US3112389

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:14:10

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:11:39
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:34:25
	(b) (4)	
User entered empty.	Matthew Musikanth	19 Nov 2020 17:08:26
	(b) (4)	

US3112389

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:14:10

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:11:39
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:34:25
	(b) (4)	
User entered '0'	Matthew Musikanth	19 Nov 2020 17:08:26
	(b) (4)	

US3112389

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:14:10

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:11:39
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:34:25
	(b) (4)	
User entered '0'	Matthew Musikanth	19 Nov 2020 17:08:26
	(b) (4)	

US3112389

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:14:10

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:11:39
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:34:25
	(b) (4)	
User entered '0'	Matthew Musikanth	19 Nov 2020 17:08:26
	(b) (4)	

US3112389

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:14:10

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:11:39
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:34:25
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Matthew Musikanth	19 Nov 2020 17:08:26
	(b) (4)	

US3112389

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:14:10

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:11:39
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:34:25
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Matthew Musikanth	19 Nov 2020 17:08:26
	(b) (4)	

US3112389

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:14:10

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:11:39
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:34:25
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	Matthew Musikanth	19 Nov 2020 17:08:26
	(b) (4)	

US3112389

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:14:10

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:11:39
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:34:25
	(b) (4)	
User entered '0'	Matthew Musikanth	19 Nov 2020 17:08:26
	(b) (4)	

US3112389

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:14:10

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:11:39
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:34:25
	(b) (4)	
User entered 'I'	Matthew Musikanth	19 Nov 2020 17:08:26
	(b) (4)	

US3112389

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:14:10

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:11:39
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:34:25
	(b) (4)	
User entered '0'	Matthew Musikanth	19 Nov 2020 17:08:26
	(b) (4)	

US3112389

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:14:10

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:11:39
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:34:25
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Matthew Musikanth	19 Nov 2020 17:08:26
	(b) (4)	

US3112389

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:14:10

[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 16:11:39
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:34:25
	(b) (4)	
User entered empty.	Matthew Musikanth	19 Nov 2020 17:08:26
	(b) (4)	

US3112389

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:14:10

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:11:39
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:34:25
	(b) (4)	
User entered empty.	Matthew Musikanth	19 Nov 2020 17:08:26
	(b) (4)	

US3112389

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:14:10

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:11:39
User entered '0'	System	19 Nov 2020 17:08:26

US3112389

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:14:10

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:11:39
User entered 'I'	System	19 Nov 2020 17:08:26

US3112389

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:14:10

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:11:39

US3112389

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:14:10

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:11:44

US3112389

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:14:10

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:11:44
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:34:25
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Viral infections NEC, PT: Viral infection, LLT: Viral syndrome - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Jan 2021 20:04:11
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Jan 2021 20:04:11
Data point term sent to Coder	System	27 Jan 2021 20:03:48
User entered 'viral syndrome'	Brenda Grande (b) (4) (b) (4)	27 Jan 2021 20:03:30

US3112389

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:14:10

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:11:44
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:34:25
User entered 'Yes (Y)'	Brenda Grande (b) (4) (b) (4)	27 Jan 2021 20:03:30

US3112389

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:14:10

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:11:44
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:34:25
User entered 'No (N)'	Brenda Grande (b) (4) (b) (4)	27 Jan 2021 20:03:30

US3112389

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:14:10

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:11:44
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:34:25
User entered 'No (N)'	Brenda Grande (b) (4) (b) (4)	27 Jan 2021 20:03:30

US3112389

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:14:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:11:44
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:34:25
User entered '15 Jan 2021'	Brenda Grande (b) (4) (b) (4)	27 Jan 2021 20:03:30

US3112389

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:14:10

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:11:44
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:34:25
User entered empty.	Brenda Grande (b) (4) (b) (4)	27 Jan 2021 20:03:30

US3112389

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:14:10

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:11:44
User entered empty.	System	27 Jan 2021 20:03:30

US3112389

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:14:10

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:11:44
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:34:25
	(b) (4)	
User entered 'No (N)' reason for change: New Information	Brenda Grande (b) (4)	22 Feb 2021 19:28:07
User entered 'Yes (Y)'	Brenda Grande (b) (4)	27 Jan 2021 20:03:30
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:14:10

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:11:44
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:34:25
	(b) (4)	
User entered '24 Jan 2021' reason for change: Data Entry Error	Brenda Grande (b) (4)	22 Feb 2021 19:28:07
User entered empty.	(b) (4)	
	Brenda Grande (b) (4)	27 Jan 2021 20:03:30
	(b) (4)	

US3112389

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:14:10

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:11:44
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:34:25
User entered empty.	Brenda Grande (b) (4) (b) (4)	27 Jan 2021 20:03:30

US3112389

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:14:10

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:11:44
User entered empty.	System	27 Jan 2021 20:03:30

US3112389

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:14:10

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:11:44
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:34:25
User entered 'Grade 1/Mild (Grade 1/Mild)'	Brenda Grande (b) (4) (b) (4)	27 Jan 2021 20:03:30

US3112389

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:14:10

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:11:44
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:34:25
User entered 'No (N)'	Brenda Grande (b) (4) (b) (4)	27 Jan 2021 20:03:30

US3112389

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:14:10

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:11:44
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:34:25
	(b) (4)	
User entered '0'	Brenda Grande (b) (4)	27 Jan 2021 20:03:30
	(b) (4)	

US3112389

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:14:10

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:11:44
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:34:25
	(b) (4)	
User entered '0'	Brenda Grande (b) (4)	27 Jan 2021 20:03:30
	(b) (4)	

US3112389

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:14:10

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:11:44
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:34:25
User entered '0'	Brenda Grande (b) (4) (b) (4)	27 Jan 2021 20:03:30

US3112389

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:14:10

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:11:44
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:34:25
User entered empty.	Brenda Grande (b) (4) (b) (4)	27 Jan 2021 20:03:30

US3112389

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:14:10

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:11:44
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:34:25
User entered empty.	Brenda Grande (b) (4) (b) (4)	27 Jan 2021 20:03:30

US3112389

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:14:10

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:11:44
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:34:25
User entered empty.	Brenda Grande (b) (4) (b) (4)	27 Jan 2021 20:03:30

US3112389

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:14:10

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:11:44
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:34:25
User entered empty.	Brenda Grande (b) (4) (b) (4)	27 Jan 2021 20:03:30

US3112389

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:14:10

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:11:44
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:34:25
	(b) (4)	
User entered '0'	Brenda Grande (b) (4)	27 Jan 2021 20:03:30
	(b) (4)	

US3112389

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:14:10

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:11:44
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:34:25
User entered '0'	Brenda Grande (b) (4) (b) (4)	27 Jan 2021 20:03:30

US3112389

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:14:10

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:11:44
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:34:25
	(b) (4)	
User entered '0'	Brenda Grande (b) (4)	27 Jan 2021 20:03:30
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:14:10

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:11:44
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:34:25
User entered 'Not Related (NOT RELATED)'	Brenda Grande (b) (4) (b) (4)	27 Jan 2021 20:03:30

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:14:10

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:11:44
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:34:25
User entered 'Not Related (NOT RELATED)'	Brenda Grande (b) (4) (b) (4)	27 Jan 2021 20:03:30

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:14:10

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:11:44
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:34:25
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	Brenda Grande (b) (4)	27 Jan 2021 20:03:30
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:14:10

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:11:44
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:34:25
	(b) (4)	
User entered 'I'	Brenda Grande (b) (4)	27 Jan 2021 20:03:30
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:14:10

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:11:44
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:34:25
	(b) (4)	
User entered '0'	Brenda Grande (b) (4)	27 Jan 2021 20:03:30
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:14:10

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:11:44
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:34:25
	(b) (4)	
User entered '0'	Brenda Grande (b) (4)	27 Jan 2021 20:03:30
	(b) (4)	

US3112389

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:14:10

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:11:44
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:34:25
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	Brenda Grande (b) (4)	22 Feb 2021 19:28:07
	(b) (4)	
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Brenda Grande (b) (4)	27 Jan 2021 20:03:30
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:14:10

[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 16:11:44
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:34:25
User entered empty.	Brenda Grande (b) (4) (b) (4)	27 Jan 2021 20:03:30

US3112389

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:14:10

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:11:44
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:34:25
User entered empty.	Brenda Grande (b) (4) (b) (4)	27 Jan 2021 20:03:30

US3112389

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:14:10

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:11:44
User entered '0'	System	27 Jan 2021 20:03:30

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:14:10

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:11:44
User entered '1'	System	27 Jan 2021 20:03:30

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:14:10

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:11:44

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:14:10

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	09 Apr 2021 00:13:43
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:29:50
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 13:11:50
User entered 'USA-US062-2021-mRNA-1273-P301000013'	System	26 Mar 2021 13:11:41
User entered 'New'	(b) (4), (b) (6)	26 Mar 2021 13:11:41

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:14:10

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	09 Apr 2021 00:13:43
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:29:53
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Soft tissue neoplasms malignant and unspecified, HLT: Liposarcomas malignant, PT: Liposarcoma, LLT: Liposarcoma - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Mar 2021 07:08:37
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Mar 2021 07:08:37
Data point term sent to Coder	System	25 Mar 2021 23:15:58
User entered 'Left Thigh Liposarcoma'	Matthew Musikanth (b) (4)	25 Mar 2021 23:15:30

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:14:10

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	09 Apr 2021 00:13:43
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:30:38
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	25 Mar 2021 23:15:30

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:14:10

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	09 Apr 2021 00:13:43
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:30:38
User entered 'No (N)'	Matthew Musikanth (b) (4)	25 Mar 2021 23:15:30

US3112389

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:14:10

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	09 Apr 2021 00:13:43
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:30:38
User entered 'No (N)'	Matthew Musikanth (b) (4)	25 Mar 2021 23:15:30

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:14:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	09 Apr 2021 00:13:43
	(b) (4)	
User closed query 'PV Query: Please confirm if event start date is 01 Feb 2020 or 01 Feb 2021.' (Site from Safety).	(b) (4), (b) (6)	07 Apr 2021 15:31:42
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:29:59
Query 'PV Query: Please confirm if event start date is 01 Feb 2020 or 01 Feb 2021.' answered with 'updated to reflect date of dx not start of growth. ' (Site from Safety).	Matthew Musikanth (b) (4)	06 Apr 2021 20:32:38
User closed query 'Adverse Event Start Date is before treatment date at Visit 1. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' (Site from System).	System	06 Apr 2021 20:32:17
User closed query 'The Start Date for Adverse Event is prior to ICF Date. Please verify if the dates are correct. If correct, the Adverse Event should be deleted from the AE eCRF and re-recorded in Medical History. Please review and clarify. ' (Site from System).	System	06 Apr 2021 20:32:17
User entered '02 Dec 2020' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	06 Apr 2021 20:32:17
User opened query 'PV Query: Please confirm if event start date is 01 Feb 2020 or 01 Feb 2021.' (Site from Safety).	(b) (4), (b) (6)	02 Apr 2021 22:53:42
User opened query 'Adverse Event Start Date is before treatment date at Visit 1. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' (Site from System).	System	29 Mar 2021 17:42:19
User opened query 'The Start Date for Adverse Event is prior to ICF Date. Please verify if the dates are correct. If correct, the Adverse Event should be deleted from the AE eCRF and re-recorded in Medical History. Please review and clarify. ' (Site from System).	System	29 Mar 2021 17:42:19
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	29 Mar 2021 17:42:19

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:14:10

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

Audit	User	Time (GMT)
User entered '01 Feb 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Mar 2021 17:42:19
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	25 Mar 2021 23:15:30
User entered 'un Feb 2020' (non-conformant).	Matthew Musikanth (b) (4)	25 Mar 2021 23:15:30

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:14:10

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	09 Apr 2021 00:13:43
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:30:38
User entered empty.	Matthew Musikanth (b) (4)	25 Mar 2021 23:15:30

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:14:10

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Mar 2021 23:15:30

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:14:10

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	09 Apr 2021 00:13:43
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:30:38
User entered 'No (N)'	Matthew Musikanth (b) (4)	25 Mar 2021 23:15:30

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:14:10

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	09 Apr 2021 00:13:43
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:30:02
User entered '09 Mar 2021'	Matthew Musikanth (b) (4)	25 Mar 2021 23:15:30

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:14:10

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	09 Apr 2021 00:13:43
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:30:38
User entered empty.	Matthew Musikanth (b) (4)	25 Mar 2021 23:15:30

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:14:10

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Mar 2021 23:15:30

US3112389

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:14:10

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	09 Apr 2021 00:13:43
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:30:38
User entered 'Grade 4 (Grade 4)'	Matthew Musikanth (b) (4)	25 Mar 2021 23:15:30

US3112389

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:14:10

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	09 Apr 2021 00:13:43
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:30:38
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	25 Mar 2021 23:15:30

US3112389

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:14:10

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	09 Apr 2021 00:13:43
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:30:38
User entered '0'	Matthew Musikanth (b) (4)	25 Mar 2021 23:15:30

US3112389

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:14:10

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	09 Apr 2021 00:13:43
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:30:38
User entered '0'	Matthew Musikanth (b) (4)	25 Mar 2021 23:15:30

US3112389

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:14:10

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	09 Apr 2021 00:13:43
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:30:38
User entered '0'	Matthew Musikanth (b) (4)	25 Mar 2021 23:15:30

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:14:10

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	09 Apr 2021 00:13:43
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:30:38
User entered empty.	Matthew Musikanth (b) (4)	25 Mar 2021 23:15:30

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:14:10

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	09 Apr 2021 00:13:43
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:30:38
User entered empty.	Matthew Musikanth (b) (4)	25 Mar 2021 23:15:30

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:14:10

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	09 Apr 2021 00:13:43
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:30:38
User entered empty.	Matthew Musikanth (b) (4)	25 Mar 2021 23:15:30

US3112389

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:14:10

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	09 Apr 2021 00:13:43
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:30:38
User entered empty.	Matthew Musikanth (b) (4)	25 Mar 2021 23:15:30

US3112389

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:14:10

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	09 Apr 2021 00:13:43
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:30:38
User entered '0'	Matthew Musikanth (b) (4)	25 Mar 2021 23:15:30

US3112389

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:14:10

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	09 Apr 2021 00:13:43
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:30:38
User entered '0'	Matthew Musikanth (b) (4)	25 Mar 2021 23:15:30

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:14:10

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	09 Apr 2021 00:13:43
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:30:38
User entered 'I'	Matthew Musikanth (b) (4)	25 Mar 2021 23:15:30

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:14:10

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	09 Apr 2021 00:13:43
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:30:38
User entered 'Not Related (NOT RELATED)'	Matthew Musikanth (b) (4)	25 Mar 2021 23:15:30

US3112389

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:14:10

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	09 Apr 2021 00:13:43
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:30:38
User entered 'Not Related (NOT RELATED)'	Matthew Musikanth (b) (4)	25 Mar 2021 23:15:30

US3112389

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:14:10

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	09 Apr 2021 00:13:43
User closed query 'PV Query: If onset date is correct, action taken with study drug was reported as not applicable. As subject received drug dosing after onset of event, please update action accordingly.' (Site from Safety). DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	07 Apr 2021 15:31:46
Query 'PV Query: If onset date is correct, action taken with study drug was reported as not applicable. As subject received drug dosing after onset of event, please update action accordingly.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6) Matthew Musikanth (b) (4)	06 Apr 2021 22:30:38
User opened query 'PV Query: If onset date is correct, action taken with study drug was reported as not applicable. As subject received drug dosing after onset of event, please update action accordingly.' (Site from Safety).	(b) (4), (b) (6)	02 Apr 2021 22:54:07
User entered 'Not Applicable (NOT APPLICABLE)'	Matthew Musikanth (b) (4)	25 Mar 2021 23:15:30

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:14:10

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	09 Apr 2021 00:13:43
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:30:38
User entered '0'	Matthew Musikanth (b) (4)	25 Mar 2021 23:15:30

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:14:10

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	09 Apr 2021 00:13:43
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:30:38
User entered '0'	Matthew Musikanth (b) (4)	25 Mar 2021 23:15:30

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:14:10

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy (i.e., Medical Treatment procedure and not diagnostic procedure) recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' (Site from DM). User signature succeeded.	(b) (4), (b) (6) (b) (4) Todd Simmons (b) (4) (b) (4)	13 Apr 2021 22:15:39 09 Apr 2021 00:13:43
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:30:38
Query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy (i.e., Medical Treatment procedure and not diagnostic procedure) recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' answered with 'updated' (Site from DM).	Matthew Musikanth (b) (4)	06 Apr 2021 20:37:19
User opened query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy (i.e., Medical Treatment procedure and not diagnostic procedure) recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	03 Apr 2021 03:12:31
User entered 'I'	Matthew Musikanth (b) (4)	25 Mar 2021 23:15:30

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:14:10

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	09 Apr 2021 00:13:43
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:30:38
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Matthew Musikanth (b) (4)	25 Mar 2021 23:15:30

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:14:10

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	09 Apr 2021 00:13:43
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:30:38
User entered empty.	Matthew Musikanth (b) (4)	25 Mar 2021 23:15:30

US3112389

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:14:10

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please confirm if this is an outpatient procedure or if subject was admitted overnight.' (Site from Safety).	(b) (4), (b) (6)	14 Apr 2021 14:43:00
User closed query 'PV Query: Was the left thigh mass (per SD began Jun 2020) reported as medical history an additional mass or the same as the event?' (Site from Safety).	(b) (4), (b) (6)	14 Apr 2021 14:42:55
User closed query 'PV Query: Medical records did not show that a COVID-19 test was done. Please confirm if it was done.' (Site from Safety).	(b) (4), (b) (6)	14 Apr 2021 14:42:52
Query 'PV Query: Was the left thigh mass (per SD began Jun 2020) reported as medical history an additional mass or the same as the event?' answered with 'Same' (Site from Safety).	Matthew Musikanth (b) (4)	13 Apr 2021 16:47:31
Query 'PV Query: Please confirm if this is an outpatient procedure or if subject was admitted overnight.' answered with 'Pt confirmed procedure was in an outpatient setting.' (Site from Safety).	Matthew Musikanth (b) (4)	13 Apr 2021 16:44:12
Query 'PV Query: Medical records did not show that a COVID-19 test was done. Please confirm if it was done.' answered with 'Pt. confirmed negative COVID-19 test prior to procedure.' (Site from Safety).	Matthew Musikanth (b) (4)	13 Apr 2021 16:43:11
User opened query 'PV Query: Please confirm if this is an outpatient procedure or if subject was admitted overnight.' (Site from Safety).	(b) (4), (b) (6)	13 Apr 2021 11:35:42
User opened query 'PV Query: Was the left thigh mass (per SD began Jun 2020) reported as medical history an additional mass or the same as the event?' (Site from Safety).	(b) (4), (b) (6)	13 Apr 2021 11:35:30
User opened query 'PV Query: Medical records did not show that a COVID-19 test was done. Please confirm if it was done.' (Site from Safety).	(b) (4), (b) (6)	13 Apr 2021 11:35:14
User closed query 'IQVIA Medical Query: Please provide the results of any COVID-19 testing performed including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	09 Apr 2021 14:47:50

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:14:10

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety). User signature succeeded.	(b) (4), (b) (6) [REDACTED] Todd Simmons (b) (4) [REDACTED] [REDACTED]	09 Apr 2021 14:47:45 09 Apr 2021 00:13:43
Query 'IQVIA Medical Query: Please provide the results of any COVID-19 testing performed including date of collection and type of testing. If not done, please state so.' answered with 'medical records sent.' (Site from Safety).	Matthew Musikanth (b) (4)	07 Apr 2021 23:05:27
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' answered with 'Medical records sent.' (Site from Safety).	Matthew Musikanth (b) (4)	07 Apr 2021 23:05:19
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6) [REDACTED]	07 Apr 2021 15:31:52
DataPoint Verified.	(b) (4), (b) (6) [REDACTED]	06 Apr 2021 22:30:38
User entered 'PT. DX AND TREATeD FOR LEFT THIGH LIPOSARCOMA. EXCISED 09MAR2021. NO FURTHER TREATMENT PLANNED AT THIS TIME. FOLLOW UP IN 6 MONTHS PER THEIR SPECIALIST.' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	06 Apr 2021 22:28:58

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:14:10

[Narrative](#)

Audit	User	Time (GMT)
User entered 'pt. dx and treated for left thigh liposarcoma. excised 09mar2021. no further treatment planned at this time. follow up in 6 months per their specialist.' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	06 Apr 2021 20:39:06
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'liposarcoma excision added to procedure. no further treatment planned. ' (Site from Safety).	Matthew Musikanth (b) (4)	06 Apr 2021 20:38:04
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.		05 Apr 2021 00:21:44
User opened query 'IQVIA Medical Query: Please provide the results of any COVID-19 testing performed including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	02 Apr 2021 22:54:40
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	02 Apr 2021 22:54:29
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	02 Apr 2021 22:54:20
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	25 Mar 2021 23:15:30

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:14:10

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	Matthew Musikanth (b) (4)	25 Mar 2021 23:15:30

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:14:10

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	25 Mar 2021 23:15:30

US3112389

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:14:10

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	25 Mar 2021 23:15:30

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 15:14:10

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:45:06
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
User closed query 'Per CDM Review: "Have you ever received facial cosmetic injections?" is checked YES on the eDiary, however, there are no Concomitant Procedures, Concomitant Medications, or Medical History capturing that this patient has ever received a cosmetic injection. Please review and update the database as appropriate or confirm if the eDiary response was in error. ' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 08:44:55
Query 'Per CDM Review: "Have you ever received facial cosmetic injections?" is checked YES on the eDiary, however, there are no Concomitant Procedures, Concomitant Medications, or Medical History capturing that this patient has ever received a cosmetic injection. Please review and update the database as appropriate or confirm if the eDiary response was in error. ' answered with 'conmed updated' (Site from DM).	Brenda Grande (b) (4) (b) (4)	23 Mar 2021 17:34:21
User opened query 'Per CDM Review: "Have you ever received facial cosmetic injections?" is checked YES on the eDiary, however, there are no Concomitant Procedures, Concomitant Medications, or Medical History capturing that this patient has ever received a cosmetic injection. Please review and update the database as appropriate or confirm if the eDiary response was in error. ' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 08:38:27
User closed query 'Per DM CLR: Per Diary Dose 1 Day 5, Headache (General) = Any use of prescription pain reliever or prevents daily 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) (6)	11 Feb 2021 14:30:56

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 15:14:10

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

Audit	User	Time (GMT)
Query 'Per DM CLR: Per Diary Dose 1 Day 5, Headache (General) = Any use of prescription pain reliever or prevents daily 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 'subject cant remember taking anything ' (Site from DM).	Brenda Grande (b) (4) (b) (4)	01 Feb 2021 21:42:31
User opened query 'Per DM CLR: Per Diary Dose 1 Day 5, Headache (General) = Any use of prescription pain reliever or prevents daily 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) (6)	12 Jan 2021 16:27:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Aug 2020 17:35:59

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:14:10

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: PRAVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:42:53
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:42:53
Data point term sent to Coder	System	27 Aug 2020 17:38:05
User entered 'Pravastatin'	(b) (4), (b) (6)	27 Aug 2020 17:37:31

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:14:10

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
User entered 'No (N)'	(b) (4), (b) (6)	27 Aug 2020 17:37:31

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:14:10

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
User entered 'Hypercholesterolemia'	(b) (4), (b) (6) (b) (4)	27 Aug 2020 17:37:31

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:14:10

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
User entered '10'	(b) (4), (b) (6)	27 Aug 2020 17:37:31

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:14:10

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
User entered 'mg (mg)'	(b) (4), (b) (6)	27 Aug 2020 17:37:31

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:14:10

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 17:37:31

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:14:10

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
User entered 'once daily (QD)'	(b) (4), (b) (6)	27 Aug 2020 17:37:31

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:14:10

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 17:37:31

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:14:10

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
User entered 'Oral (ORAL)'	(b) (4), (b) (6) (b) (4)	27 Aug 2020 17:37:31

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:14:10

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 17:37:31

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:14:10

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

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
User entered 'UN UNK 2020'	(b) (4), (b) (6) (b) (4)	27 Aug 2020 17:37:31

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:14:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
User entered '0'	(b) (4), (b) (6)	27 Aug 2020 17:37:31

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:14:10

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Aug 2020 17:37:31

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:14:10

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 17:37:31

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:14:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
User entered 'No (N)'	(b) (4), (b) (6)	27 Aug 2020 17:37:31

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:14:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Aug 2020 17:37:31

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:14:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Aug 2020 17:37:31

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:14:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	27 Aug 2020 17:37:31

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:14:10

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: ESTROGENS, ATC: NATURAL AND SEMISYNTHETIC ESTROGENS, PLAIN, PRODUCT: ESTRADIOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Sep 2020 16:55:38
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Sep 2020 16:55:38
User coded data point as ATC: ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS, ATC: ENDOCRINE THERAPY, ATC: HORMONES AND RELATED AGENTS, ATC: ESTROGENS, PRODUCT: ESTRADIOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Aug 2020 00:51:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Aug 2020 00:51:51
Data point term sent to Coder	System	27 Aug 2020 17:43:14
Data point term sent to Coder	System	27 Aug 2020 17:40:09
User entered 'Estradiol'	(b) (4), (b) (6) (b) (4)	27 Aug 2020 17:39:38

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:14:10

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
User entered 'No (N)'	(b) (4), (b) (6)	27 Aug 2020 17:39:38

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:14:10

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
User entered 'POST MENOPAUSAL HOT FLAshes' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Aug 2020 17:42:55
User entered 'Post Menopausal Hot Flahses'	(b) (4), (b) (6)	27 Aug 2020 17:39:38

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:14:10

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
User entered '2'	(b) (4), (b) (6)	27 Aug 2020 17:39:38

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:14:10

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
User entered 'mg (mg)'	(b) (4), (b) (6)	27 Aug 2020 17:39:38

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:14:10

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 17:39:38

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:14:10

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
User entered 'as needed (PRN)'	(b) (4), (b) (6) (b) (4), (b) (6)	27 Aug 2020 17:39:38

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:14:10

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 17:39:38

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:14:10

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
User entered 'Oral (ORAL)'	(b) (4), (b) (6) (b) (4), (b) (6)	27 Aug 2020 17:39:38

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:14:10

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 17:39:38

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:14:10

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
User entered 'UN UNK 2019'	(b) (4), (b) (6) (b) (4), (b) (6)	27 Aug 2020 17:39:38

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:14:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
User entered '0'	(b) (4), (b) (6)	27 Aug 2020 17:39:38

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:14:10

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Aug 2020 17:39:38

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:14:10

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 17:39:38

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:14:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
User entered 'No (N)'	(b) (4), (b) (6)	27 Aug 2020 17:39:38

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:14:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Aug 2020 17:39:38

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:14:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Aug 2020 17:39:38

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:14:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Aug 2020 17:39:38

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:14:10

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:43:01
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:43:01
Data point term sent to Coder	System	27 Aug 2020 17:40:10
User entered 'Multivitamin'	(b) (4), (b) (6)	27 Aug 2020 17:40:06

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:14:10

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Aug 2020 17:40:06

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:14:10

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
User entered 'Supplement'	(b) (4), (b) (6) (b) (4), (b) (6)	27 Aug 2020 17:40:06

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:14:10

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
User entered '1'	(b) (4), (b) (6)	27 Aug 2020 17:40:06

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:14:10

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
User entered 'tablet (TABLET)'	(b) (4), (b) (6) (b) (4), (b) (6)	27 Aug 2020 17:40:06

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:14:10

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Aug 2020 17:40:06

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:14:10

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
User entered 'once daily (QD)'	(b) (4), (b) (6) (b) (4), (b) (6)	27 Aug 2020 17:40:06

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:14:10

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Aug 2020 17:40:06

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:14:10

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	27 Aug 2020 17:40:06

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:14:10

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 17:40:06

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:14:10

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

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
User entered 'UN UNK 2000'	(b) (4), (b) (6) (b) (4)	27 Aug 2020 17:40:06

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:14:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
User entered '0'	(b) (4), (b) (6) (b) (4), (b) (6)	27 Aug 2020 17:40:06

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:14:10

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4), (b) (6)	27 Aug 2020 17:40:06

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:14:10

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 17:40:06

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:14:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
User entered 'No (N)'	(b) (4), (b) (6)	27 Aug 2020 17:40:06

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:14:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Aug 2020 17:40:06

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:14:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Aug 2020 17:40:06

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:14:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	27 Aug 2020 17:40:06

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:14:10

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: VITAMIN D NOS, PRODUCTSYNONYM: VITAMIN D [VITAMIN D NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:43:05
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:43:05
Data point term sent to Coder	System	27 Aug 2020 17:41:11
User entered 'Vitamin D'	(b) (4), (b) (6)	27 Aug 2020 17:40:38

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:14:10

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
User entered 'No (N)'	(b) (4), (b) (6)	27 Aug 2020 17:40:38

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:14:10

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
User entered 'Supplement'	(b) (4), (b) (6) (b) (4), (b) (6)	27 Aug 2020 17:40:38

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:14:10

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
User entered '2000'	(b) (4), (b) (6)	27 Aug 2020 17:40:38

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:14:10

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
User entered 'IU (IU)'	(b) (4), (b) (6) (b) (4), (b) (6)	27 Aug 2020 17:40:38

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:14:10

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 17:40:38

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:14:10

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
User entered 'once daily (QD)'	(b) (4), (b) (6)	27 Aug 2020 17:40:38

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:14:10

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Aug 2020 17:40:38

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:14:10

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
User entered 'Oral (ORAL)'	(b) (4), (b) (6) (b) (4), (b) (6)	27 Aug 2020 17:40:38

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:14:10

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 17:40:38

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:14:10

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
User entered 'UN UNK 2018'	(b) (4), (b) (6)	27 Aug 2020 17:40:38

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:14:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
User entered '0'	(b) (4), (b) (6)	27 Aug 2020 17:40:38

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:14:10

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4), (b) (6)	27 Aug 2020 17:40:38

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:14:10

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Aug 2020 17:40:38

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:14:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
User entered 'No (N)'	(b) (4), (b) (6)	27 Aug 2020 17:40:38

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:14:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Aug 2020 17:40:38

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:14:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Aug 2020 17:40:38

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:14:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	27 Aug 2020 17:40:38

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:14:10

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: OTHER PLAIN VITAMIN PREPARATIONS, ATC: OTHER PLAIN VITAMIN PREPARATIONS, PRODUCT: VITAMIN E NOS, PRODUCTSYNONYM: VITAMIN E [VITAMIN E NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:43:24
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:43:24
Data point term sent to Coder	System	27 Aug 2020 17:42:13
User entered 'Vitamin E'	(b) (4), (b) (6)	27 Aug 2020 17:41:23

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:14:10

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
User entered 'No (N)'	(b) (4), (b) (6) (b) (4), (b) (6)	27 Aug 2020 17:41:23

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:14:10

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
User entered 'Supplement'	(b) (4), (b) (6) (b) (4), (b) (6)	27 Aug 2020 17:41:23

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:14:10

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
User entered '400'	(b) (4), (b) (6)	27 Aug 2020 17:41:23

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:14:10

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
User entered 'mg (mg)'	(b) (4), (b) (6)	27 Aug 2020 17:41:23

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:14:10

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Aug 2020 17:41:23

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:14:10

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
User entered 'every other day (QOD)'	(b) (4), (b) (6) (b) (4), (b) (6)	27 Aug 2020 17:41:23

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:14:10

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 17:41:23

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:14:10

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	27 Aug 2020 17:41:23

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:14:10

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 17:41:23

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:14:10

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
User entered 'UN UNK 2015'	(b) (4), (b) (6) (b) (4), (b) (6)	27 Aug 2020 17:41:23

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:14:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
User entered '0'	(b) (4), (b) (6) (b) (4), (b) (6)	27 Aug 2020 17:41:23

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:14:10

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4), (b) (6)	27 Aug 2020 17:41:23

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:14:10

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Aug 2020 17:41:23

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:14:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
User entered 'No (N)'	(b) (4), (b) (6) (b) (4), (b) (6)	27 Aug 2020 17:41:23

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:14:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Aug 2020 17:41:23

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:14:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	27 Aug 2020 17:41:23

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:14:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	27 Aug 2020 17:41:23

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:14:10

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: OTHER ANTIINFLAMMATORY AND ANTIRHEUMATIC AGENTS, NON-STEROIDS, PRODUCT: GLUCOSAMINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Aug 2020 19:43:24
	(b) (4)	
User coded data point as Term Coded data point by	Coder Import (b) (4)	27 Aug 2020 19:43:24
User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	
Data point term sent to Coder	System	27 Aug 2020 17:42:13
User entered 'Glucosamine'	(b) (4), (b) (6)	27 Aug 2020 17:41:58

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:14:10

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
User entered 'No (N)'	(b) (4), (b) (6) (b) (4), (b) (6)	27 Aug 2020 17:41:58

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:14:10

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
User entered 'Supplement'	(b) (4), (b) (6) (b) (4), (b) (6)	27 Aug 2020 17:41:58

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:14:10

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
User entered '2'	(b) (4), (b) (6)	27 Aug 2020 17:41:58

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:14:10

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
User entered 'tablet (TABLET)'	(b) (4), (b) (6) (b) (4), (b) (6)	27 Aug 2020 17:41:58

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:14:10

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 17:41:58

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:14:10

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
User entered 'once daily (QD)'	(b) (4), (b) (6) (b) (4), (b) (6)	27 Aug 2020 17:41:58

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:14:10

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Aug 2020 17:41:58

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:14:10

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
User entered 'Oral (ORAL)'	(b) (4), (b) (6) (b) (4)	27 Aug 2020 17:41:58

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:14:10

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 17:41:58

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:14:10

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
User entered 'UN UNK 2015'	(b) (4), (b) (6)	27 Aug 2020 17:41:58

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:14:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
User entered '0'	(b) (4), (b) (6) (b) (4), (b) (6)	27 Aug 2020 17:41:58

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:14:10

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Aug 2020 17:41:58

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:14:10

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Aug 2020 17:41:58

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:14:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
User entered 'No (N)'	(b) (4), (b) (6)	27 Aug 2020 17:41:58

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:14:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Aug 2020 17:41:58

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:14:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Aug 2020 17:41:58

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:14:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	27 Aug 2020 17:41:58

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:14:10

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: ASCORBIC ACID (VITAMIN C), INCL. COMBINATIONS, ATC: ASCORBIC ACID (VITAMIN C), PLAIN, PRODUCT: ASCORBIC ACID, PRODUCTSYNONYM: VITAMIN C [ASCORBIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:43:25
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:43:25
Data point term sent to Coder	System	27 Aug 2020 17:43:14
User entered 'Vitamin C'	(b) (4), (b) (6)	27 Aug 2020 17:42:28

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:14:10

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
User entered 'No (N)'	(b) (4), (b) (6)	27 Aug 2020 17:42:28

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:14:10

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
User entered 'Supplement'	(b) (4), (b) (6) (b) (4), (b) (6)	27 Aug 2020 17:42:28

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:14:10

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
User entered '2015'	(b) (4), (b) (6)	27 Aug 2020 17:42:28

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:14:10

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
User entered 'mg (mg)'	(b) (4), (b) (6)	27 Aug 2020 17:42:28

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:14:10

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 17:42:28

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:14:10

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
User entered 'once daily (QD)'	(b) (4), (b) (6)	27 Aug 2020 17:42:28

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:14:10

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 17:42:28

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:14:10

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	27 Aug 2020 17:42:28

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:14:10

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Aug 2020 17:42:28

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:14:10

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
User entered 'UN UNK 2015'	(b) (4), (b) (6)	27 Aug 2020 17:42:28

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:14:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
User entered '0'	(b) (4), (b) (6) (b) (4), (b) (6)	27 Aug 2020 17:42:28

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:14:10

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Aug 2020 17:42:28

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:14:10

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 17:42:28

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:14:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
User entered 'No (N)'	(b) (4), (b) (6)	27 Aug 2020 17:42:28

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:14:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Aug 2020 17:42:28

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:14:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Aug 2020 17:42:28

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:14:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	27 Aug 2020 17:42:28

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:14:10

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:15:50
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Jan 2021 18:11:54
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Jan 2021 18:11:54
Data point term sent to Coder	System	26 Jan 2021 18:11:12
Coding entries removed.	Natalie Moy (b) (4) (b) (4)	26 Jan 2021 18:10:49
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 17:11:02
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 17:11:02
Data point term sent to Coder	System	19 Nov 2020 17:10:05
User entered 'Flu Vaccine'	Matthew Musikanth (b) (4)	19 Nov 2020 17:09:12

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:14:10

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:15:50
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'Yes (Y)'	Matthew Musikanth	19 Nov 2020 17:09:12
	(b) (4)	

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:14:10

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:15:50
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'Flu Prophylaxis'	Matthew Musikanth	19 Nov 2020 17:09:12
	(b) (4)	

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:14:10

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:15:50
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered '.5'	Matthew Musikanth	19 Nov 2020 17:09:12
	(b) (4)	

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:14:10

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:15:50
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
User entered 'mL (mL)'	Matthew Musikanth (b) (4)	19 Nov 2020 17:09:12

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:14:10

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:15:50
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered empty.	Matthew Musikanth	19 Nov 2020 17:09:12
	(b) (4)	

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:14:10

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:15:50
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'once (ONCE)'	Matthew Musikanth	19 Nov 2020 17:09:12
	(b) (4)	

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:14:10

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:15:50
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered empty.	Matthew Musikanth	19 Nov 2020 17:09:12
	(b) (4)	

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:14:10

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:15:50
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
User closed query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 19:06:17
Query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' answered with 'updated thank you ' (Site from DM).	Natalie Moy (b) (4) (b) (4)	26 Jan 2021 18:10:55
User entered 'Intramuscular (INTRAMUSCULAR)' reason for change: Data Entry Error	Natalie Moy (b) (4) (b) (4)	26 Jan 2021 18:10:49
User opened query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 01:50:53
User entered 'Oral (ORAL)'	Matthew Musikanth (b) (4)	19 Nov 2020 17:09:12

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:14:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:15:50
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered empty.	Matthew Musikanth	19 Nov 2020 17:09:12
	(b) (4)	

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:14:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:15:50
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
User entered '20 Oct 2020'	Matthew Musikanth (b) (4)	19 Nov 2020 17:09:12

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:14:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:15:50
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered '0'	Matthew Musikanth	19 Nov 2020 17:09:12
	(b) (4)	

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:14:10

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:15:50
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'No (N)'	Matthew Musikanth	19 Nov 2020 17:09:12
	(b) (4)	

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:14:10

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:15:50
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered '20 Oct 2020'	Matthew Musikanth	19 Nov 2020 17:09:12
	(b) (4)	

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:14:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:15:50
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'No (N)'	Matthew Musikanth	19 Nov 2020 17:09:12
	(b) (4)	

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:14:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:15:50
User entered empty.	System	19 Nov 2020 17:09:12

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:14:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:15:50
User entered empty.	System	19 Nov 2020 17:09:12

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:14:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:15:50
User entered empty.	System	19 Nov 2020 17:09:12

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:14:10

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:15:54
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: NITROFURAN DERIVATIVES, PRODUCT: NITROFURANTOIN, PRODUCTSYNONYM: MACROBID [NITROFURANTOIN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 17:11:01
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 17:11:01
Data point term sent to Coder	System	19 Nov 2020 17:10:05
User entered 'Macrobid'	Matthew Musikanth (b) (4)	19 Nov 2020 17:09:43

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:14:10

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:15:54
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'No (N)'	Matthew Musikanth	19 Nov 2020 17:09:43
	(b) (4)	

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:14:10

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:15:54
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'UTI'	Matthew Musikanth	19 Nov 2020 17:09:43
	(b) (4)	

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:14:10

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:15:54
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered '100'	Matthew Musikanth	19 Nov 2020 17:09:43
	(b) (4)	

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:14:10

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:15:54
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'mg (mg)'	Matthew Musikanth	19 Nov 2020 17:09:43
	(b) (4)	

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:14:10

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:15:54
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered empty.	Matthew Musikanth	19 Nov 2020 17:09:43
	(b) (4)	

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:14:10

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:15:54
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'twice daily (BID)'	Matthew Musikanth	19 Nov 2020 17:09:43
	(b) (4)	

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:14:10

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:15:54
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered empty.	Matthew Musikanth	19 Nov 2020 17:09:43
	(b) (4)	

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:14:10

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:15:54
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'Oral (ORAL)'	Matthew Musikanth	19 Nov 2020 17:09:43
	(b) (4)	

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:14:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:15:54
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered empty.	Matthew Musikanth	19 Nov 2020 17:09:43
	(b) (4)	

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:14:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:15:54
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered '10 Nov 2020'	Matthew Musikanth	19 Nov 2020 17:09:43
	(b) (4)	

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:14:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:15:54
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered '0'	Matthew Musikanth	19 Nov 2020 17:09:43
	(b) (4)	

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:14:10

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:15:54
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'No (N)'	Matthew Musikanth	19 Nov 2020 17:09:43
	(b) (4)	

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:14:10

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:15:54
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered '15 Nov 2020'	Matthew Musikanth	19 Nov 2020 17:09:43
	(b) (4)	

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:14:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:15:54
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'No (N)'	Matthew Musikanth	19 Nov 2020 17:09:43
	(b) (4)	

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:14:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:15:54
User entered '2'	System	19 Nov 2020 17:09:43

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:14:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:15:54
User entered '1'	System	19 Nov 2020 17:09:43

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:14:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:15:54
User entered '804 (804)'	System	19 Nov 2020 17:09:43

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:14:10

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:15:46
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: BACTERIAL VACCINES, ATC: PNEUMOCOCCAL VACCINES, PRODUCT: PNEUMOCOCCAL VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Dec 2020 18:10:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Dec 2020 18:10:44
Data point term sent to Coder	System	22 Dec 2020 21:53:27
User entered 'pneumococcal vaccine'	Karen Mylerberg (b) (4) (b) (4)	22 Dec 2020 21:53:11

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:14:10

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:15:46
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
User entered 'Yes (Y)'	Karen Mylerberg (b) (4) (b) (4)	22 Dec 2020 21:53:11

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:14:10

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:15:46
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'pneumonia prevention prophylaxis'	Karen Mylerberg (b) (4)	22 Dec 2020 21:53:11
	(b) (4)	

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:14:10

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:15:46
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
User entered '0.5'	Karen Mylerberg (b) (4) (b) (4)	22 Dec 2020 21:53:11

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:14:10

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:15:46
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
User entered 'mL (mL)'	Karen Mylerberg (b) (4) (b) (4)	22 Dec 2020 21:53:11

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:14:10

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:15:46
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered empty.	Karen Mylerberg (b) (4)	22 Dec 2020 21:53:11
	(b) (4)	

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:14:10

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:15:46
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'once (ONCE)'	Karen Mylerberg (b) (4)	22 Dec 2020 21:53:11
	(b) (4)	

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:14:10

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:15:46
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
User entered empty.	Karen Mylerberg (b) (4) (b) (4)	22 Dec 2020 21:53:11

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:14:10

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:15:46
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'Intramuscular (INTRAMUSCULAR)'	Karen Mylerberg (b) (4)	22 Dec 2020 21:53:11
	(b) (4)	

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:14:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:15:46
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered empty.	Karen Mylerberg (b) (4)	22 Dec 2020 21:53:11
	(b) (4)	

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:14:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:15:46
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered '02 Dec 2020'	Karen Mylerberg (b) (4)	22 Dec 2020 21:53:11
	(b) (4)	

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:14:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:15:46
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered '0'	Karen Mylerberg (b) (4)	22 Dec 2020 21:53:11
	(b) (4)	

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:14:10

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:15:46
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'No (N)'	Karen Mylerberg (b) (4)	22 Dec 2020 21:53:11
	(b) (4)	

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:14:10

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:15:46
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered '02 Dec 2020'	Karen Mylerberg (b) (4)	22 Dec 2020 21:53:11
	(b) (4)	

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:14:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:15:46
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
User entered 'No (N)'	Karen Mylerberg (b) (4) (b) (4)	22 Dec 2020 21:53:11

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:14:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:15:46
User entered empty.	System	22 Dec 2020 21:53:11

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:14:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:15:46
User entered empty.	System	22 Dec 2020 21:53:11

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:14:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:15:46
User entered empty.	System	22 Dec 2020 21:53:11

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:14:10

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:44:09
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User coded data point as ATC: DERMATOLOGICALS, ATC: OTHER DERMATOLOGICAL PREPARATIONS, ATC: OTHER DERMATOLOGICAL PREPARATIONS, ATC: OTHER DERMATOLOGICALS, PRODUCT: BOTULINUM TOXIN TYPE A, PRODUCTSYNONYM: BOTOX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Mar 2021 17:37:40
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Mar 2021 17:37:40
	(b) (4)	
Data point term sent to Coder	System	23 Mar 2021 17:36:55
User entered 'botox'	Brenda Grande (b) (4)	23 Mar 2021 17:36:55
	(b) (4)	

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:14:10

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:44:09
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'No (N)'	Brenda Grande (b) (4)	23 Mar 2021 17:36:55
	(b) (4)	

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:14:10

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:44:09
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'cosmetic'	Brenda Grande (b) (4)	23 Mar 2021 17:36:55
	(b) (4)	

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:14:10

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:44:09
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'unknown'	Brenda Grande (b) (4)	23 Mar 2021 17:36:55
	(b) (4)	

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:14:10

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:44:09
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
User entered 'Other (OTHER)'	Brenda Grande (b) (4) (b) (4)	23 Mar 2021 17:36:55

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:14:10

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:44:09
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'unknown'	Brenda Grande (b) (4)	23 Mar 2021 17:36:55
	(b) (4)	

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:14:10

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:44:09
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'once (ONCE)'	Brenda Grande (b) (4)	23 Mar 2021 17:36:55
	(b) (4)	

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:14:10

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:44:09
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered empty.	Brenda Grande (b) (4)	23 Mar 2021 17:36:55
	(b) (4)	

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:14:10

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:44:09
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'Subcutaneous (SUBCUTANEOUS)'	Brenda Grande (b) (4)	23 Mar 2021 17:36:55
	(b) (4)	

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:14:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:44:09
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered empty.	Brenda Grande (b) (4)	23 Mar 2021 17:36:55
	(b) (4)	

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:14:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:44:09
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'un UNK 2017'	Brenda Grande (b) (4)	23 Mar 2021 17:36:55
	(b) (4)	

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:14:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:44:09
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered '0'	Brenda Grande (b) (4)	23 Mar 2021 17:36:55
	(b) (4)	

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:14:10

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:44:09
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'No (N)'	Brenda Grande (b) (4)	23 Mar 2021 17:36:55
	(b) (4)	

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:14:10

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:44:09
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'un UNK 2017'	Brenda Grande (b) (4)	23 Mar 2021 17:36:55
	(b) (4)	

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:14:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:44:09
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
User entered 'No (N)'	Brenda Grande (b) (4) (b) (4)	23 Mar 2021 17:36:55

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:14:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:44:09
User entered empty.	System	23 Mar 2021 17:36:55

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:14:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:44:09
User entered empty.	System	23 Mar 2021 17:36:55

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:14:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:44:09
User entered empty.	System	23 Mar 2021 17:36:55

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:14:10

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:44:14
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
User coded data point as ATC: DERMATOLOGICALS, ATC: OTHER DERMATOLOGICAL PREPARATIONS, ATC: OTHER DERMATOLOGICAL PREPARATIONS, ATC: OTHER DERMATOLOGICALS, PRODUCT: HYALURONIC ACID, PRODUCTS SYNONYM: JUVEDERM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Mar 2021 17:39:02
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Mar 2021 17:39:02
Data point term sent to Coder	System	23 Mar 2021 17:37:59
User entered 'Juvederm'	Brenda Grande (b) (4) (b) (4)	23 Mar 2021 17:37:47

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:14:10

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:44:14
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'No (N)'	Brenda Grande (b) (4)	23 Mar 2021 17:37:47
	(b) (4)	

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:14:10

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:44:14
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'cosmetic'	Brenda Grande (b) (4)	23 Mar 2021 17:37:47
	(b) (4)	

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:14:10

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:44:14
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'unknown'	Brenda Grande (b) (4)	23 Mar 2021 17:37:47
	(b) (4)	

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:14:10

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:44:14
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'Other (OTHER)'	Brenda Grande (b) (4)	23 Mar 2021 17:37:47
	(b) (4)	

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:14:10

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:44:14
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'unknown'	Brenda Grande (b) (4)	23 Mar 2021 17:37:47
	(b) (4)	

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:14:10

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:44:14
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'once (ONCE)'	Brenda Grande (b) (4)	23 Mar 2021 17:37:47
	(b) (4)	

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:14:10

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:44:14
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered empty.	Brenda Grande (b) (4)	23 Mar 2021 17:37:47
	(b) (4)	

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:14:10

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:44:14
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'Subcutaneous (SUBCUTANEOUS)'	Brenda Grande (b) (4)	23 Mar 2021 17:37:47
	(b) (4)	

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:14:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:44:14
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered empty.	Brenda Grande (b) (4)	23 Mar 2021 17:37:47
	(b) (4)	

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:14:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:44:14
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'un UNK 2015'	Brenda Grande (b) (4)	23 Mar 2021 17:37:47
	(b) (4)	

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:14:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:44:14
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered '0'	Brenda Grande (b) (4)	23 Mar 2021 17:37:47
	(b) (4)	

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:14:10

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:44:14
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'No (N)'	Brenda Grande (b) (4)	23 Mar 2021 17:37:47
	(b) (4)	

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:14:10

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:44:14
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered 'un UNK 2015'	Brenda Grande (b) (4)	23 Mar 2021 17:37:47
	(b) (4)	

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:14:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:44:14
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
User entered 'No (N)'	Brenda Grande (b) (4) (b) (4)	23 Mar 2021 17:37:47

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:14:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:44:14
User entered empty.	System	23 Mar 2021 17:37:47

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:14:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:44:14
User entered empty.	System	23 Mar 2021 17:37:47

US3112389

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:14:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:44:14
User entered empty.	System	23 Mar 2021 17:37:47

US3112389

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 15:14:10

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:45:06
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	09 Apr 2021 00:13:43
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:27:31
Signature has been broken.	Matthew Musikanth (b) (4)	06 Apr 2021 20:36:39
User entered 'Yes (Y)' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	06 Apr 2021 20:36:39
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
User entered 'No (N)'	Karen Mylerberg (b) (4) (b) (4)	19 Feb 2021 16:12:00

US3112389

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:14:10

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	09 Apr 2021 00:13:43
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:27:45
User entered '09 Mar 2021'	Matthew Musikanth (b) (4)	06 Apr 2021 20:37:06

US3112389

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:14:10

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	09 Apr 2021 00:13:43
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:27:45
User entered 'Liposarcoma excision'	Matthew Musikanth (b) (4)	06 Apr 2021 20:37:06

US3112389

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:14:10

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	09 Apr 2021 00:13:43
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:27:45
User entered 'Adverse Event (AE)'	Matthew Musikanth (b) (4)	06 Apr 2021 20:37:06

US3112389

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:14:10

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	09 Apr 2021 00:13:43
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:27:45
User entered empty.	Matthew Musikanth (b) (4)	06 Apr 2021 20:37:06

US3112389

Folder: SAE USA-US062-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:14:10

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:25:44
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 13:11:59
User entered	System	26 Mar 2021 13:11:41
'USA-US062-2021-MRNA-1273-P301000013'		

US3112389

Folder: SAE USA-US062-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:14:10

[Serious](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:25:44
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 13:11:59
User entered 'Yes (Y)'	System	26 Mar 2021 13:11:41

US3112389

Folder: SAE USA-US062-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:14:10

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:25:44
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 13:11:59
User entered 'No (N)'	System	26 Mar 2021 13:11:41

US3112389

Folder: SAE USA-US062-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:14:10

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:25:44
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 13:11:59
User entered 'No (N)'	System	26 Mar 2021 13:11:41

US3112389

Folder: SAE USA-US062-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:14:10

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:25:44
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 13:11:59
User entered 'No (N)'	System	26 Mar 2021 13:11:41

US3112389

Folder: SAE USA-US062-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:14:10

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:25:44
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 13:11:59
User entered 'No (N)'	System	26 Mar 2021 13:11:41

US3112389

Folder: SAE USA-US062-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:14:10

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:25:44
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 13:11:59
User entered 'No (N)'	System	26 Mar 2021 13:11:41

US3112389

Folder: SAE USA-US062-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:14:10

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:25:44
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 13:11:59
User entered 'Yes (Y)'	System	26 Mar 2021 13:11:41

US3112389

Folder: SAE USA-US062-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:14:10

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:25:44
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 13:11:59
User entered 'Todd'	System	26 Mar 2021 13:11:41

US3112389

Folder: SAE USA-US062-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:14:10

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:25:44
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 13:11:59
User entered 'Simmons'	System	26 Mar 2021 13:11:41

US3112389

Folder: SAE USA-US062-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:14:10

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:25:44
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 13:11:59
User entered '9040 Friars Road Suite 540'	System	26 Mar 2021 13:11:41

US3112389

Folder: SAE USA-US062-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:14:10

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:25:44
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 13:11:59
User entered 'San Diego'	System	26 Mar 2021 13:11:41

US3112389

Folder: SAE USA-US062-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:14:10

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:25:44
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 13:11:59
User entered 'CA'	System	26 Mar 2021 13:11:41

US3112389

Folder: SAE USA-US062-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:14:10

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:25:44
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 13:11:59
User entered '92108'	System	26 Mar 2021 13:11:41

US3112389

Folder: SAE USA-US062-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:14:10

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:25:44
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 12:51:46
User entered 'US'	System	26 Mar 2021 13:12:10

US3112389

Folder: SAE USA-US062-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:14:10

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	12 Apr 2021 15:30:08
User entered '3'	System	07 Apr 2021 15:32:43
User entered '2'	System	30 Mar 2021 12:52:04
User entered '1'	System	26 Mar 2021 13:12:10

US3112389

Folder: SAE USA-US062-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:14:10

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:25:44
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 13:11:59
User entered 'USA-US062-2021-MRNA-1273-P301000013'	System	26 Mar 2021 13:11:41

US3112389

Folder: SAE USA-US062-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:14:10

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:25:44
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 13:11:59
User entered 'Yes (Y)'	System	26 Mar 2021 13:11:41

US3112389

Folder: SAE USA-US062-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:14:10

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:25:44
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 13:11:59
User entered 'No (N)'	System	26 Mar 2021 13:11:41

US3112389

Folder: SAE USA-US062-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:14:10

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:25:44
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 13:11:59
User entered 'No (N)'	System	26 Mar 2021 13:11:41

US3112389

Folder: SAE USA-US062-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:14:10

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:25:44
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 13:11:59
User entered 'No (N)'	System	26 Mar 2021 13:11:41

US3112389

Folder: SAE USA-US062-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:14:10

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:25:44
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 13:11:59
User entered 'No (N)'	System	26 Mar 2021 13:11:41

US3112389

Folder: SAE USA-US062-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:14:10

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:25:44
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 13:11:59
User entered 'No (N)'	System	26 Mar 2021 13:11:41

US3112389

Folder: SAE USA-US062-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:14:10

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:25:44
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 13:11:59
User entered 'Yes (Y)'	System	26 Mar 2021 13:11:41

US3112389

Folder: SAE USA-US062-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:14:10

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:25:44
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 13:11:59
User entered 'Todd'	System	26 Mar 2021 13:11:41

US3112389

Folder: SAE USA-US062-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:14:10

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:25:44
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 13:11:59
User entered 'Simmons'	System	26 Mar 2021 13:11:41

US3112389

Folder: SAE USA-US062-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:14:10

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:25:44
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 13:11:59
User entered '9040 Friars Road Suite 540'	System	26 Mar 2021 13:11:41

US3112389

Folder: SAE USA-US062-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:14:10

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:25:44
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 13:11:59
User entered 'San Diego'	System	26 Mar 2021 13:11:41

US3112389

Folder: SAE USA-US062-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:14:10

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:25:44
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 13:11:59
User entered 'CA'	System	26 Mar 2021 13:11:41

US3112389

Folder: SAE USA-US062-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:14:10

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:25:44
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 13:11:59
User entered '92108'	System	26 Mar 2021 13:11:41

US3112389

Folder: SAE USA-US062-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:14:10

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:25:44
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 12:51:46
User entered 'US'	System	26 Mar 2021 13:12:10

US3112389

Folder: SAE USA-US062-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:14:10

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	12 Apr 2021 15:30:08
User entered '3'	System	07 Apr 2021 15:32:43
User entered '2'	System	30 Mar 2021 12:52:04
User entered '1'	System	26 Mar 2021 13:12:10

US3112389

Folder: SAE USA-US062-2021-MRNA-1273-P301000013

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:14:10

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:25:44
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered '26/Mar/2021 06:12'	System	26 Mar 2021 13:12:10

US3112389

Folder: SAE USA-US062-2021-MRNA-1273-P301000013

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:14:10

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:25:44
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 12:51:46
User entered 'I'	(b) (4), (b) (6)	26 Mar 2021 13:12:10

US3112389

Folder: SAE USA-US062-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:14:10

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:25:44
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 13:11:59
User entered 'USA-US062-2021-MRNA-1273-P301000013'	System	26 Mar 2021 13:11:41

US3112389

Folder: SAE USA-US062-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:14:10

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:25:44
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 13:11:59
User entered 'Yes (Y)'	System	26 Mar 2021 13:11:41

US3112389

Folder: SAE USA-US062-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:14:10

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:25:44
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 13:11:59
User entered 'No (N)'	System	26 Mar 2021 13:11:41

US3112389

Folder: SAE USA-US062-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:14:10

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:25:44
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 13:11:59
User entered 'No (N)'	System	26 Mar 2021 13:11:41

US3112389

Folder: SAE USA-US062-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:14:10

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:25:44
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 13:11:59
User entered 'No (N)'	System	26 Mar 2021 13:11:41

US3112389

Folder: SAE USA-US062-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:14:10

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:25:44
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 13:11:59
User entered 'No (N)'	System	26 Mar 2021 13:11:41

US3112389

Folder: SAE USA-US062-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:14:10

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:25:44
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 13:11:59
User entered 'No (N)'	System	26 Mar 2021 13:11:41

US3112389

Folder: SAE USA-US062-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:14:10

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:25:44
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 13:11:59
User entered 'Yes (Y)'	System	26 Mar 2021 13:11:41

US3112389

Folder: SAE USA-US062-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:14:10

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:25:44
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 13:11:59
User entered 'Todd'	System	26 Mar 2021 13:11:41

US3112389

Folder: SAE USA-US062-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:14:10

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:25:44
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 13:11:59
User entered 'Simmons'	System	26 Mar 2021 13:11:41

US3112389

Folder: SAE USA-US062-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:14:10

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:25:44
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 13:11:59
User entered '9040 Friars Road Suite 540'	System	26 Mar 2021 13:11:41

US3112389

Folder: SAE USA-US062-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:14:10

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:25:44
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 13:11:59
User entered 'San Diego'	System	26 Mar 2021 13:11:41

US3112389

Folder: SAE USA-US062-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:14:10

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:25:44
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 13:11:59
User entered 'CA'	System	26 Mar 2021 13:11:41

US3112389

Folder: SAE USA-US062-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:14:10

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:25:44
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 13:11:59
User entered '92108'	System	26 Mar 2021 13:11:41

US3112389

Folder: SAE USA-US062-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:14:10

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:25:44
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 12:51:46
User entered 'US'	System	26 Mar 2021 13:12:10

US3112389

Folder: SAE USA-US062-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:14:10

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	12 Apr 2021 15:30:08
User entered '3'	System	07 Apr 2021 15:32:43
User entered '2'	System	30 Mar 2021 12:52:04
User entered '1'	System	26 Mar 2021 13:12:10

US3112389

Folder: SAE USA-US062-2021-MRNA-1273-P301000013

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:14:10

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:25:44
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
User entered '30/Mar/2021 08:52'	System	30 Mar 2021 12:52:04

US3112389

Folder: SAE USA-US062-2021-MRNA-1273-P301000013

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:14:10

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)
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 15:32:27
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:25:44
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
User entered 'I'	(b) (4), (b) (6)	30 Mar 2021 12:52:04

US3112389

Folder: SAE USA-US062-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:14:10

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:25:44
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 13:11:59
User entered 'USA-US062-2021-MRNA-1273-P301000013'	System	26 Mar 2021 13:11:41

US3112389

Folder: SAE USA-US062-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:14:10

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:25:44
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 13:11:59
User entered 'Yes (Y)'	System	26 Mar 2021 13:11:41

US3112389

Folder: SAE USA-US062-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:14:10

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:25:44
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 13:11:59
User entered 'No (N)'	System	26 Mar 2021 13:11:41

US3112389

Folder: SAE USA-US062-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:14:10

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:25:44
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 13:11:59
User entered 'No (N)'	System	26 Mar 2021 13:11:41

US3112389

Folder: SAE USA-US062-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:14:10

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:25:44
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 13:11:59
User entered 'No (N)'	System	26 Mar 2021 13:11:41

US3112389

Folder: SAE USA-US062-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:14:10

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:25:44
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 13:11:59
User entered 'No (N)'	System	26 Mar 2021 13:11:41

US3112389

Folder: SAE USA-US062-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:14:10

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:25:44
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 13:11:59
User entered 'No (N)'	System	26 Mar 2021 13:11:41

US3112389

Folder: SAE USA-US062-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:14:10

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:25:44
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 13:11:59
User entered 'Yes (Y)'	System	26 Mar 2021 13:11:41

US3112389

Folder: SAE USA-US062-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:14:10

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:25:44
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 13:11:59
User entered 'Todd'	System	26 Mar 2021 13:11:41

US3112389

Folder: SAE USA-US062-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:14:10

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:25:44
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 13:11:59
User entered 'Simmons'	System	26 Mar 2021 13:11:41

US3112389

Folder: SAE USA-US062-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:14:10

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:25:44
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 13:11:59
User entered '9040 Friars Road Suite 540'	System	26 Mar 2021 13:11:41

US3112389

Folder: SAE USA-US062-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:14:10

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:25:44
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 13:11:59
User entered 'San Diego'	System	26 Mar 2021 13:11:41

US3112389

Folder: SAE USA-US062-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:14:10

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:25:44
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 13:11:59
User entered 'CA'	System	26 Mar 2021 13:11:41

US3112389

Folder: SAE USA-US062-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:14:10

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:25:44
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 13:11:59
User entered '92108'	System	26 Mar 2021 13:11:41

US3112389

Folder: SAE USA-US062-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:14:10

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:25:44
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 12:51:46
User entered 'US'	System	26 Mar 2021 13:12:10

US3112389

Folder: SAE USA-US062-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:14:10

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	12 Apr 2021 15:30:08
User entered '3'	System	07 Apr 2021 15:32:43
User entered '2'	System	30 Mar 2021 12:52:04
User entered '1'	System	26 Mar 2021 13:12:10

US3112389

Folder: SAE USA-US062-2021-MRNA-1273-P301000013

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:14:10

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	09 Apr 2021 00:13:43
User entered '07/Apr/2021 11:32'	System	07 Apr 2021 15:32:43

US3112389

Folder: SAE USA-US062-2021-MRNA-1273-P301000013

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:14:10

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.	Todd Simmons (b) (4) (b) (4)	09 Apr 2021 00:13:43
User entered 'I'	(b) (4), (b) (6)	07 Apr 2021 15:32:43

US3112389

Folder: SAE USA-US062-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:14:10

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:25:44
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 13:11:59
User entered	System	26 Mar 2021 13:11:41
'USA-US062-2021-MRNA-1273-P301000013'		

US3112389

Folder: SAE USA-US062-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:14:10

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:25:44
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 13:11:59
User entered 'Yes (Y)'	System	26 Mar 2021 13:11:41

US3112389

Folder: SAE USA-US062-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:14:10

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:25:44
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 13:11:59
User entered 'No (N)'	System	26 Mar 2021 13:11:41

US3112389

Folder: SAE USA-US062-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:14:10

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:25:44
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 13:11:59
User entered 'No (N)'	System	26 Mar 2021 13:11:41

US3112389

Folder: SAE USA-US062-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:14:10

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:25:44
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 13:11:59
User entered 'No (N)'	System	26 Mar 2021 13:11:41

US3112389

Folder: SAE USA-US062-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:14:10

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:25:44
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 13:11:59
User entered 'No (N)'	System	26 Mar 2021 13:11:41

US3112389

Folder: SAE USA-US062-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:14:10

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:25:44
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 13:11:59
User entered 'No (N)'	System	26 Mar 2021 13:11:41

US3112389

Folder: SAE USA-US062-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:14:10

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:25:44
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 13:11:59
User entered 'Yes (Y)'	System	26 Mar 2021 13:11:41

US3112389

Folder: SAE USA-US062-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:14:10

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:25:44
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 13:11:59
User entered 'Todd'	System	26 Mar 2021 13:11:41

US3112389

Folder: SAE USA-US062-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:14:10

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:25:44
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 13:11:59
User entered 'Simmons'	System	26 Mar 2021 13:11:41

US3112389

Folder: SAE USA-US062-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:14:10

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:25:44
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 13:11:59
User entered '9040 Friars Road Suite 540'	System	26 Mar 2021 13:11:41

US3112389

Folder: SAE USA-US062-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:14:10

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:25:44
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 13:11:59
User entered 'San Diego'	System	26 Mar 2021 13:11:41

US3112389

Folder: SAE USA-US062-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:14:10

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:25:44
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 13:11:59
User entered 'CA'	System	26 Mar 2021 13:11:41

US3112389

Folder: SAE USA-US062-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:14:10

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:25:44
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 22:02:25
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 13:11:59
User entered '92108'	System	26 Mar 2021 13:11:41

US3112389

Folder: SAE USA-US062-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:14:10

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:25:44
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 22:02:25
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 12:51:46
User entered 'US'	System	26 Mar 2021 13:12:10

US3112389

Folder: SAE USA-US062-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:14:10

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	12 Apr 2021 15:30:08
User entered '3'	System	07 Apr 2021 15:32:43
User entered '2'	System	30 Mar 2021 12:52:04
User entered '1'	System	26 Mar 2021 13:12:10

US3112389

Folder: SAE USA-US062-2021-MRNA-1273-P301000013

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 15:14:10

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	15 Apr 2021 23:40:44
	(b) (4)	
User entered '12/Apr/2021 11:30'	System	12 Apr 2021 15:30:08

US3112389

Folder: SAE USA-US062-2021-MRNA-1273-P301000013

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 15:14:10

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.	Todd Simmons (b) (4) (b) (4)	15 Apr 2021 23:40:44
User entered 'I'	(b) (4), (b) (6)	12 Apr 2021 15:30:08