

US3212394 (Prod: DM Clinical Research - ERN - PPDS)

Generated By: KC Joubran

Generated On: 09 Jun 2021 15:51:18

All time stamps listed in this document are displayed in GMT

US3212394

Form: Participant Creation

Data signed: (b) (4) 06 Apr 2021 15:32:26

Generated On: 09 Jun 2021 15:51:18

Participant ID

US3212394

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

US3212394

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 06 Apr 2021 15:32:32

Generated On: 09 Jun 2021 15:51:18

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	11 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	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 06 Apr 2021 15:32:32

Generated On: 09 Jun 2021 15:51:18

Date of Birth (MMM yyyy)	(b) (6) 1957
Age	62
Age Units	YEARS
Age (Derived)	62
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	False
Black	True
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

US3212394

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 06 Apr 2021 15:32:32

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Date of Informed Consent (dd MMM yyyy) 11 SEP 2020

Month and Year of Informed Consent (derived) SEP 2020

Year of Informed Consent (derived) 2020

Protocol Version

Amendment 1 ☐

Amendment 2 ☐

Amendment 3 ☒

Amendment 4 ☐

Amendment 5 ☐

Was participant enrolled in the study? Yes ☒
No ☐

If No, indicate reason for screen fail

Withdrew Consent ☐

Inclusion/Exclusion ☐

Cohort Full ☐

Other ☐

If reason for screen fail is Other, specify _____

Was this participant screened previously? Yes ☐
No ☒

If Yes, previous participant number _____

Enrollment Trigger 1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 06 Apr 2021 15:32:32

Generated On: 09 Jun 2021 15:51:18

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 06 Apr 2021 15:32:32

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Were any significant conditions reported?

Yes ☒
No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 06 Apr 2021 15:32:32

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Condition	MYOMECTOMY
Start date (dd MMM yyyy)	UN UNK 1995
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1995
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1995
Start Year (derived)	1995
Stop Month and Year (derived)	JAN 1995
Stop Year (derived)	1995

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 06 Apr 2021 15:32:32

Generated On: 09 Jun 2021 15:51:18

Condition	CESAREAN SECTION
Start date (dd MMM yyyy)	UN UNK 1985
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1985
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1985
Start Year (derived)	1985
Stop Month and Year (derived)	JAN 1985
Stop Year (derived)	1985

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 06 Apr 2021 15:32:32

Generated On: 09 Jun 2021 15:51:18

Condition	APPENDECTOMY
Start date (dd MMM yyyy)	UN UNK 1998
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1998
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1998
Start Year (derived)	1998
Stop Month and Year (derived)	JAN 1998
Stop Year (derived)	1998

US3212394

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 06 Apr 2021 15:32:32

Generated On: 09 Jun 2021 15:51:18

Condition	APPENDICITIS
Start date (dd MMM yyyy)	UN UNK 1998
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1998
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1998
Start Year (derived)	1998
Stop Month and Year (derived)	JAN 1998
Stop Year (derived)	1998

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 06 Apr 2021 15:32:32

Generated On: 09 Jun 2021 15:51:18

Condition	UTERINE FIBROIDS
Start date (dd MMM yyyy)	UN UNK 1990
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1995
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1990
Start Year (derived)	1990
Stop Month and Year (derived)	JAN 1995
Stop Year (derived)	1995

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 06 Apr 2021 15:32:32

Generated On: 09 Jun 2021 15:51:18

Condition	POST-MENOPAUSAL
Start date (dd MMM yyyy)	UN UNK 2000
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 2000
Start Year (derived)	2000
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 06 Apr 2021 15:32:32

Generated On: 09 Jun 2021 15:51:18

Condition	HEART MURMUR
Start date (dd MMM yyyy)	UN UNK 2015
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 2015
Start Year (derived)	2015
Stop Month and Year (derived)	
Stop Year (derived)	

US3212394

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 06 Apr 2021 15:32:32

Generated On: 09 Jun 2021 15:51:18

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	11 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	13:50 (24 HR)
Vital Signs Date and Time (derived)	11 SEP 2020 13:50
Height (<i>xxx.x</i>)	65 in
Weight (<i>xxx.x</i>)	230.6 lb
BMI (<i>xxx.x</i>)	38.45408 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) 06 Apr 2021 15:32:32

Generated On: 09 Jun 2021 15:51:18

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

11 SEP 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) 06 Apr 2021 15:32:32

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Date of assessment (dd MMM yyyy) 11 SEP 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) UN UNK 2000

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 06 Apr 2021 15:32:32

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Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☒ No ☐

Specify NURSE

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 06 Apr 2021 15:32:32

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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)	True
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)	False
Other	True
Specify	PARTICIPANT ATTENDED LARGE GROUP EVENTS IN THE PAST FEW WEEKS (E.G., WEDDING, PLACES OF WORSHIP, CONCERT)

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 06 Apr 2021 15:32:32

Generated On: 09 Jun 2021 15:51:18

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	11 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	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 06 Apr 2021 15:32:32

Generated On: 09 Jun 2021 15:51:18

What was the date of randomization? (dd MMM yyyy) 11 SEP 2020

What was the participant's randomization number? 113573

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) 06 Apr 2021 15:32:32

Generated On: 09 Jun 2021 15:51:18

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) 06 Apr 2021 15:32:32

Generated On: 09 Jun 2021 15:51:18

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)	11 SEP 2020
Time of assessment (00:00-23:59)	13:50 (24 HR)
Vital Signs Date and Time (derived)	11 SEP 2020 13:50
Temperature (xxx.x)	97.5 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	96 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 06 Apr 2021 15:32:32

Generated On: 09 Jun 2021 15:51:18

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)	11 SEP 2020
Time of assessment (00:00-23:59)	17:42 (24 HR)
Vital Signs Date and Time (derived)	11 SEP 2020 17:42
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)	95 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	145 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: Physical Examination

Data signed: (b) (4) 06 Apr 2021 15:32:32

Generated On: 09 Jun 2021 15:51:18

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) 06 Apr 2021 15:32:32

Generated On: 09 Jun 2021 15:51:18

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) 11 SEP 2020

What was the treatment time? (00:00-23:59) 17:00 (24 HR)

Treatment Date and Time (derived) 11 SEP 2020 17:00

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) 06 Apr 2021 15:32:32

Generated On: 09 Jun 2021 15:51:18

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

Collection date (dd MMM yyyy)	11 SEP 2020
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Collection time (00:00-23:59)	15:31 (24 HR)
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Collection date and time (derived)	11 SEP 2020 15:31
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US3212394

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 06 Apr 2021 15:32:32

Generated On: 09 Jun 2021 15:51:18

Collection date (dd MMM yyyy)			11 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	15:09	11 SEP 2020 15:09
Nasopharyngeal Swab 2	No		

US3212394

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 06 Apr 2021 15:32:32

Generated On: 09 Jun 2021 15:51:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212394

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °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

11 SEP 2020 17:41

PC Open Date & Time

11 SEP 2020 17:20

PC Close Date & Time

11 SEP 2020 19:50

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:51:18

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 ☒

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

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

PC Time Stamp	12 SEP 2020 07:32
PC Open Date & Time	11 SEP 2020 20:45
PC Close Date & Time	12 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °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

12 SEP 2020 17:04

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °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

13 SEP 2020 18:04

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3212394

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °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

14 SEP 2020 18:04

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3212394

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:51:18

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.6 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

To TREAT pain or fever that has already occurred	True
To PREVENT pain or fever from occurring	False

PC Time Stamp	15 SEP 2020 15:18
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3212394

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 SEP 2020 17:06

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3212394

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °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

17 SEP 2020 18:04

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3212394

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:51:18

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

11 SEP 2020 17:42

PC Open Date & Time

11 SEP 2020 17:20

PC Close Date & Time

11 SEP 2020 19:50

US3212394

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

12 SEP 2020 07:30

PC Open Date & Time

11 SEP 2020 20:45

PC Close Date & Time

12 SEP 2020 11:59

US3212394

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:51:18

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 ☐

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

50

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)**

50

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

12 SEP 2020 17:09

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3212394

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:51:18

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 ☐

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

50

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)**

50

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

13 SEP 2020 18:04

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3212394

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:51:18

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)**

50

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)**

50

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

14 SEP 2020 18:05

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3212394

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:51:18

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)**

50

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

15 SEP 2020 15:20

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3212394

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:51:18

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 ☐

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

5

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

16 SEP 2020 17:07

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3212394

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:51:18

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 ☐

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

5

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

17 SEP 2020 18:04

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3212394

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:51:18

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 ☐

US3212394

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:51:18

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

No ☒

Yes ☐

PC Time stamp	11 SEP 2020 17:42
PC Open Date & Time	11 SEP 2020 17:20
PC Close Date & Time	11 SEP 2020 19:50

US3212394

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:51:18

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 ☐

US3212394

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:51:18

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

No ☒

Yes ☐

PC Time stamp	12 SEP 2020 07:31
PC Open Date & Time	11 SEP 2020 20:45
PC Close Date & Time	12 SEP 2020 11:59

US3212394

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:51:18

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 ☒

US3212394

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:51:18

Yes <input type="checkbox"/>	
PC Time stamp	12 SEP 2020 17:10
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3212394

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

51 of 2837

EAB) (1725)

US3212394

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:51:18

Yes <input type="checkbox"/>	
PC Time stamp	13 SEP 2020 18:05
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3212394

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:51:18

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

53 of 2837

EAB) (1725)

US3212394

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:51:18

Yes <input type="checkbox"/>	
PC Time stamp	14 SEP 2020 18:05
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3212394

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3212394

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:51:18

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

US3212394

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:51:18

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

57 of 2837

EAB) (1725)

US3212394

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:51:18

Yes <input type="checkbox"/>	
PC Time stamp	16 SEP 2020 17:08
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

US3212394

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:51:18

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 ☒

US3212394

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:51:18

Yes <input type="checkbox"/>	
PC Time stamp	17 SEP 2020 18:05
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

US3212394

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(8)

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

DAY 8

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 ☐

PC Time Stamp 18 SEP 2020 18:46

PC Open Date & Time 18 SEP 2020 12:00

PC Close Date & Time 19 SEP 2020 11:59

US3212394

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(9)

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

DAY 9

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 ☐

PC Time Stamp 19 SEP 2020 12:02

PC Open Date & Time 19 SEP 2020 12:00

PC Close Date & Time 20 SEP 2020 11:59

US3212394

Folder: Diary Dose 1 (1)

Form: Redness_Day(8)

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT	DAY 8
Is there any REDNESS AT INJECTION SITE?	Yes <input type="checkbox"/>
	No <input checked="" type="checkbox"/>
PC Time Stamp	18 SEP 2020 18:46
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

US3212394

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 15:51:18

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 18 SEP 2020 18:46

PC Open Date & Time 18 SEP 2020 12:00

PC Close Date & Time 19 SEP 2020 11:59

US3212394

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:51:18

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	18 SEP 2020 18:46
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

US3212394

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT	DAY 9
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	19 SEP 2020 12:02
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

US3212394

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 06 Apr 2021 15:32:32

Generated On: 09 Jun 2021 15:51:18

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3212394

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 06 Apr 2021 15:32:32

Generated On: 09 Jun 2021 15:51:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212394

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 06 Apr 2021 15:32:31

Generated On: 09 Jun 2021 15:51:18

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 25 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3212394

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 06 Apr 2021 15:32:31

Generated On: 09 Jun 2021 15:51:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212394

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 06 Apr 2021 15:32:31

Generated On: 09 Jun 2021 15:51:18

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 02 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3212394

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 06 Apr 2021 15:32:31

Generated On: 09 Jun 2021 15:51:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212394

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 06 Apr 2021 15:32:32

Generated On: 09 Jun 2021 15:51:18

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

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

Folder OID	VISIT2
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US3212394

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 06 Apr 2021 15:32:32

Generated On: 09 Jun 2021 15:51:18

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	12 OCT 2020
Time of assessment (00:00-23:59)	09:10 (24 HR)
Vital Signs Date and Time (derived)	12 OCT 2020 09:10
Temperature (xxx.x)	97.5 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	95 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	108 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	79 mmHg
Diastolic Blood Pressure units	MMHG

US3212394

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 06 Apr 2021 15:32:32

Generated On: 09 Jun 2021 15:51:18

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)	12 OCT 2020
Time of assessment (00:00-23:59)	11:00 (24 HR)
Vital Signs Date and Time (derived)	12 OCT 2020 11:00
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	97 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	108 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	66 mmHg
Diastolic Blood Pressure units	MMHG

US3212394

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 06 Apr 2021 15:32:32

Generated On: 09 Jun 2021 15:51:18

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

12 OCT 2020

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

US3212394

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 06 Apr 2021 15:32:32

Generated On: 09 Jun 2021 15:51:18

Was study treatment given? Yes ☒
No ☐

If No, reason not given

Participant declined due to Adverse Event ☐
Physician withheld dose due to Adverse Event ☐
Death ☐
Lost To Follow-Up ☐
Physician Decision ☐
Pregnancy ☐
Protocol Deviation ☐
Study Terminated by Sponsor ☐
Withdrawal of Consent by Participant ☐
Confirmed COVID-19 ☐
Other ☐

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 12 OCT 2020

What was the treatment time? (00:00-23:59) 10:25 (24 HR)

Treatment Date and Time (derived) 12 OCT 2020 10:25

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

US3212394

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 06 Apr 2021 15:32:32

Generated On: 09 Jun 2021 15:51:18

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

12 OCT 2020

Collection time (00:00-23:59)

10:11 (24 HR)

Collection date and time (derived)

12 OCT 2020 10:11

US3212394

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 06 Apr 2021 15:32:32

Generated On: 09 Jun 2021 15:51:18

Collection date (dd MMM yyyy)			12 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:05	12 OCT 2020 10:05
Nasopharyngeal Swab 2	No		

US3212394

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 06 Apr 2021 15:32:32

Generated On: 09 Jun 2021 15:51:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212394

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °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

12 OCT 2020 11:01

PC Open Date & Time

12 OCT 2020 10:45

PC Close Date & Time

12 OCT 2020 13:15

US3212394

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 99.5 °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	12 OCT 2020 20:34
PC Open Date & Time	12 OCT 2020 14:10
PC Close Date & Time	13 OCT 2020 11:59

US3212394

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 OCT 2020 16:57

PC Open Date & Time

13 OCT 2020 12:00

PC Close Date & Time

14 OCT 2020 11:59

US3212394

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:51:18

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

98.9 °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

14 OCT 2020 17:32

PC Open Date & Time

14 OCT 2020 12:00

PC Close Date & Time

15 OCT 2020 11:59

US3212394

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 OCT 2020 17:48

PC Open Date & Time

15 OCT 2020 12:00

PC Close Date & Time

16 OCT 2020 11:59

US3212394

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °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

16 OCT 2020 19:42

PC Open Date & Time

16 OCT 2020 12:00

PC Close Date & Time

17 OCT 2020 11:59

US3212394

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.7 °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

17 OCT 2020 20:32

PC Open Date & Time

17 OCT 2020 12:00

PC Close Date & Time

18 OCT 2020 11:59

US3212394

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

18 OCT 2020 17:20

PC Open Date & Time

18 OCT 2020 12:00

PC Close Date & Time

19 OCT 2020 11:59

US3212394

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:51:18

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

12 OCT 2020 11:01

PC Open Date & Time

12 OCT 2020 10:45

PC Close Date & Time

12 OCT 2020 13:15

US3212394

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

12 OCT 2020 20:34

PC Open Date & Time

12 OCT 2020 14:10

PC Close Date & Time

13 OCT 2020 11:59

US3212394

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:51:18

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

13 OCT 2020 16:57

PC Open Date & Time

13 OCT 2020 12:00

PC Close Date & Time

14 OCT 2020 11:59

US3212394

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:51:18

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

14 OCT 2020 17:32

PC Open Date & Time

14 OCT 2020 12:00

PC Close Date & Time

15 OCT 2020 11:59

US3212394

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

15 OCT 2020 17:48

PC Open Date & Time

15 OCT 2020 12:00

PC Close Date & Time

16 OCT 2020 11:59

US3212394

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

DAY 5

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

16 OCT 2020 19:42

PC Open Date & Time

16 OCT 2020 12:00

PC Close Date & Time

17 OCT 2020 11:59

US3212394

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

17 OCT 2020 20:33

PC Open Date & Time

17 OCT 2020 12:00

PC Close Date & Time

18 OCT 2020 11:59

US3212394

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

18 OCT 2020 17:20

PC Open Date & Time

18 OCT 2020 12:00

PC Close Date & Time

19 OCT 2020 11:59

US3212394

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:51:18

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 ☐

US3212394

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:51:18

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

No ☒

Yes ☐

PC Time stamp	12 OCT 2020 11:02
PC Open Date & Time	12 OCT 2020 10:45
PC Close Date & Time	12 OCT 2020 13:15

US3212394

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:51:18

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 ☐

US3212394

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:51:18

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

No ☒

Yes ☐

PC Time stamp	12 OCT 2020 20:35
PC Open Date & Time	12 OCT 2020 14:10
PC Close Date & Time	13 OCT 2020 11:59

US3212394

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:51:18

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)

US3212394

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:51:18

Yes <input type="checkbox"/>	
PC Time stamp	13 OCT 2020 16:58
PC Open Date & Time	13 OCT 2020 12:00
PC Close Date & Time	14 OCT 2020 11:59

US3212394

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3212394

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:51:18

Yes <input type="checkbox"/>	
PC Time stamp	14 OCT 2020 17:43
PC Open Date & Time	14 OCT 2020 12:00
PC Close Date & Time	15 OCT 2020 11:59

US3212394

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3212394

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:51:18

Yes <input type="checkbox"/>	
PC Time stamp	15 OCT 2020 17:48
PC Open Date & Time	15 OCT 2020 12:00
PC Close Date & Time	16 OCT 2020 11:59

US3212394

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3212394

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:51:18

Yes <input type="checkbox"/>	
PC Time stamp	16 OCT 2020 19:42
PC Open Date & Time	16 OCT 2020 12:00
PC Close Date & Time	17 OCT 2020 11:59

US3212394

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3212394

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:51:18

Yes <input type="checkbox"/>	
PC Time stamp	17 OCT 2020 20:33
PC Open Date & Time	17 OCT 2020 12:00
PC Close Date & Time	18 OCT 2020 11:59

US3212394

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:51:18

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)

US3212394

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:51:18

Yes <input type="checkbox"/>	
PC Time stamp	18 OCT 2020 17:20
PC Open Date & Time	18 OCT 2020 12:00
PC Close Date & Time	19 OCT 2020 11:59

US3212394

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 06 Apr 2021 15:32:32

Generated On: 09 Jun 2021 15:51:18

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3212394

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 06 Apr 2021 15:32:31

Generated On: 09 Jun 2021 15:51:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212394

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 06 Apr 2021 15:32:32

Generated On: 09 Jun 2021 15:51:18

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3212394

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 06 Apr 2021 15:32:32

Generated On: 09 Jun 2021 15:51:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212394

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 06 Apr 2021 15:32:32

Generated On: 09 Jun 2021 15:51:18

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 02 NOV 2020

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

Comments

If Contact Not Made, please provide Comments

US3212394

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 06 Apr 2021 15:32:32

Generated On: 09 Jun 2021 15:51:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212394

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 06 Apr 2021 15:32:33

Generated On: 09 Jun 2021 15:51:18

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	13 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3212394

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 06 Apr 2021 15:32:33

Generated On: 09 Jun 2021 15:51:18

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	13 NOV 2020
Time of assessment (00:00-23:59)	14:37 (24 HR)
Vital Signs Date and Time (derived)	13 NOV 2020 14:37
Temperature (xxx.x)	97.5 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	94 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	113 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3212394

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 06 Apr 2021 15:32:33

Generated On: 09 Jun 2021 15:51:18

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

13 NOV 2020

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

US3212394

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 06 Apr 2021 15:32:32

Generated On: 09 Jun 2021 15:51:18

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

13 NOV 2020

Collection time (00:00-23:59)

15:36 (24 HR)

Collection date and time (derived)

13 NOV 2020 15:36

US3212394

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 06 Apr 2021 15:32:32

Generated On: 09 Jun 2021 15:51:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212394

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	11 NOV 2020 17:19:04
Patient Cloud Open Date & Time	11 NOV 2020 00:01
Patient Cloud Close Date & Time	15 NOV 2020 23:59

US3212394

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT	DAY 71
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	False
Chills	False
Cough	False
Shortness of breath	False
Difficulty breathing	False
Fatigue	True
Muscle aches	False
Body aches	False
Headache	True
New loss of taste	False
New loss of smell	False
Sore throat	False
Congestion	False
Runny nose	False
Nausea	False
Vomiting	False
Diarrhea	False
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	18 NOV 2020 00:04:12
Patient Cloud Open Date & Time	18 NOV 2020 00:01
Patient Cloud Close Date & Time	22 NOV 2020 23:59

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT	DAY 75
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	False
Chills	False
Cough	False
Shortness of breath	True
Difficulty breathing	True
Fatigue	True
Muscle aches	True
Body aches	False
Headache	True
New loss of taste	False
New loss of smell	False
Sore throat	False
Congestion	False
Runny nose	False
Nausea	False
Vomiting	False
Diarrhea	True
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	23 NOV 2020 17:09:44
Patient Cloud Open Date & Time	22 NOV 2020 00:01
PRODUCTION RELEASE (v12.003 EAB) (1725)	
126 of 2837	

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Close Date & Time](#)

26 NOV 2020 23:59

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

DAY 82

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

No ☒

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 NOV 2020 17:09:01

Patient Cloud Open Date & Time

29 NOV 2020 00:01

Patient Cloud Close Date & Time

03 DEC 2020 23:59

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

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	08 DEC 2020 12:16:34
Patient Cloud Open Date & Time	06 DEC 2020 00:01
Patient Cloud Close Date & Time	10 DEC 2020 23:59

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

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	15 DEC 2020 12:12:40
Patient Cloud Open Date & Time	13 DEC 2020 00:01
Patient Cloud Close Date & Time	17 DEC 2020 23:59

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

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

20 DEC 2020 00:02:42

Patient Cloud Open Date & Time

20 DEC 2020 00:01

Patient Cloud Close Date & Time

24 DEC 2020 23:59

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

DAY 110

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 DEC 2020 15:22:14

Patient Cloud Open Date & Time

27 DEC 2020 00:01

Patient Cloud Close Date & Time

31 DEC 2020 23:59

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 JAN 2021 02:48:43

Patient Cloud Open Date & Time

03 JAN 2021 00:01

Patient Cloud Close Date & Time

07 JAN 2021 23:59

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	14 JAN 2021 11:11:38
Patient Cloud Open Date & Time	10 JAN 2021 00:01
Patient Cloud Close Date & Time	14 JAN 2021 23:59

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 JAN 2021 12:18:12

Patient Cloud Open Date & Time

17 JAN 2021 00:01

Patient Cloud Close Date & Time

21 JAN 2021 23:59

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

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

24 JAN 2021 02:01:31

Patient Cloud Open Date & Time

24 JAN 2021 00:01

Patient Cloud Close Date & Time

28 JAN 2021 23:59

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

31 JAN 2021 14:24:52

Patient Cloud Open Date & Time

31 JAN 2021 00:01

Patient Cloud Close Date & Time

04 FEB 2021 23:59

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

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

10 FEB 2021 11:55:19

Patient Cloud Open Date & Time

07 FEB 2021 00:01

Patient Cloud Close Date & Time

11 FEB 2021 23:59

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

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	14 FEB 2021 00:01:32
Patient Cloud Open Date & Time	14 FEB 2021 00:01
Patient Cloud Close Date & Time	18 FEB 2021 23:59

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 FEB 2021 22:28:55

Patient Cloud Open Date & Time

21 FEB 2021 00:01

Patient Cloud Close Date & Time

25 FEB 2021 23:59

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

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

28 FEB 2021 15:07:00

Patient Cloud Open Date & Time

28 FEB 2021 00:01

Patient Cloud Close Date & Time

04 MAR 2021 23:59

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

09 MAR 2021 11:33:13

Patient Cloud Open Date & Time

07 MAR 2021 00:01

Patient Cloud Close Date & Time

11 MAR 2021 23:59

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	15 MAR 2021 11:11:08
Patient Cloud Open Date & Time	14 MAR 2021 00:01
Patient Cloud Close Date & Time	18 MAR 2021 23:59

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	25 MAR 2021 10:15:49
Patient Cloud Open Date & Time	21 MAR 2021 00:01
Patient Cloud Close Date & Time	25 MAR 2021 23:59

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	29 MAR 2021 17:48:32
Patient Cloud Open Date & Time	28 MAR 2021 00:01
Patient Cloud Close Date & Time	01 APR 2021 23:59

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

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

04 APR 2021 08:48:15

Patient Cloud Open Date & Time

04 APR 2021 00:01

Patient Cloud Close Date & Time

08 APR 2021 23:59

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

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

15 APR 2021 11:14:56

Patient Cloud Open Date & Time

11 APR 2021 00:01

Patient Cloud Close Date & Time

15 APR 2021 23:59

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

DAY 222

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

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

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

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

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

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

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

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

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

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

18 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

22 APR 2021 23:59

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

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

26 APR 2021 14:30:10

Patient Cloud Open Date & Time

25 APR 2021 00:01

Patient Cloud Close Date & Time

29 APR 2021 23:59

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

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

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

06 MAY 2021 23:59

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

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

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

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

[Patient Cloud Close Date & Time](#)

13 MAY 2021 23:59

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

DAY 250

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

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

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

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

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

[Patient Cloud Close Date & Time](#)

20 MAY 2021 23:59

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

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 ☐

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

27 MAY 2021 23:59

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

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

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

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

[Patient Cloud Open Date & Time](#)

30 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

03 JUN 2021 23:59

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

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 ☐

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

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

06 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

10 JUN 2021 23:59

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

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 ☐

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

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

[Patient Cloud Close Date & Time](#)

17 JUN 2021 23:59

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

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 ☐
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 ☐

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

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

[Patient Cloud Close Date & Time](#)

24 JUN 2021 23:59

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

DAY 292

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

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

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

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

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

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

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

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

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

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

[Patient Cloud Close Date & Time](#)

01 JUL 2021 23:59

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

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 ☐

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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 JUL 2021 00:01
Patient Cloud Close Date & Time	08 JUL 2021 23:59

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

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 ☐

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

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

11 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

15 JUL 2021 23:59

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

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 ☐

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

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

[Patient Cloud Close Date & Time](#)

22 JUL 2021 23:59

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

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

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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 JUL 2021 00:01
Patient Cloud Close Date & Time	29 JUL 2021 23:59

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

DAY 327

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

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

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

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

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

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

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

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

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

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

[Patient Cloud Close Date & Time](#)

05 AUG 2021 23:59

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

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 ☐
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 ☐

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

12 AUG 2021 23:59

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

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

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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 AUG 2021 00:01
Patient Cloud Close Date & Time	19 AUG 2021 23:59

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

DAY 348

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

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

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

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

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

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

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

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

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

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

[Patient Cloud Close Date & Time](#)

26 AUG 2021 23:59

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

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°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 ☐

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

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

[Patient Cloud Close Date & Time](#)

02 SEP 2021 23:59

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

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"/>

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

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

[Patient Cloud Close Date & Time](#)

09 SEP 2021 23:59

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

DAY 369

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

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

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

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 ☐

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

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

[Patient Cloud Close Date & Time](#)

23 SEP 2021 23:59

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

DAY 383

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

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

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

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

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

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

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

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

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

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

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

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 ☐

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

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

[Patient Cloud Close Date & Time](#)

07 OCT 2021 23:59

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

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 ☐

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

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

Date and time of submission	
Patient Cloud Open Date & Time	10 OCT 2021 00:01
Patient Cloud Close Date & Time	14 OCT 2021 23:59

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

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"/>

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

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

[Patient Cloud Close Date & Time](#)

21 OCT 2021 23:59

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

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="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"/>

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

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

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

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 ☐

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

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

[Patient Cloud Open Date & Time](#)

31 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

04 NOV 2021 23:59

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

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 ☐

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

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

[Patient Cloud Close Date & Time](#)

11 NOV 2021 23:59

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

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 ☐

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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 NOV 2021 00:01
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Patient Cloud Close Date & Time	18 NOV 2021 23:59
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US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

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 ☐

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 NOV 2021 00:01
Patient Cloud Close Date & Time	25 NOV 2021 23:59

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

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

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

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

[Patient Cloud Close Date & Time](#)

02 DEC 2021 23:59

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

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 ☐

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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 DEC 2021 00:01
Patient Cloud Close Date & Time	09 DEC 2021 23:59

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

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 ☐
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 ☐

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	12 DEC 2021 00:01
Patient Cloud Close Date & Time	16 DEC 2021 23:59

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

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 ☐

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

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

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

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 ☐

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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 DEC 2021 00:01
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Patient Cloud Close Date & Time	30 DEC 2021 23:59
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US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

DAY 481

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

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

[Patient Cloud Close Date & Time](#)

06 JAN 2022 23:59

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

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 ☐

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JAN 2022 23:59

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

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 ☐

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

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

[Patient Cloud Close Date & Time](#)

20 JAN 2022 23:59

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

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 ☐

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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 JAN 2022 00:01
Patient Cloud Close Date & Time	27 JAN 2022 23:59

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

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 ☐

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	30 JAN 2022 00:01
Patient Cloud Close Date & Time	03 FEB 2022 23:59

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT	DAY 516
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

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

[Patient Cloud Close Date & Time](#)

10 FEB 2022 23:59

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

DAY 523

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

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

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

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

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

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

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

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

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

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

[Patient Cloud Close Date & Time](#)

17 FEB 2022 23:59

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

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

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

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

[Patient Cloud Open Date & Time](#)

20 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

24 FEB 2022 23:59

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

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 ☐

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

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

[Patient Cloud Close Date & Time](#)

03 MAR 2022 23:59

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

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 ☐

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

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

[Patient Cloud Close Date & Time](#)

10 MAR 2022 23:59

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

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 <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"/>

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

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

[Patient Cloud Close Date & Time](#)

17 MAR 2022 23:59

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

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 ☐

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

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

[Patient Cloud Open Date & Time](#)

20 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

24 MAR 2022 23:59

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

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 ☐

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

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

[Patient Cloud Close Date & Time](#)

31 MAR 2022 23:59

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

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 ☐

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	03 APR 2022 00:01
Patient Cloud Close Date & Time	07 APR 2022 23:59

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

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 ☐

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

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

[Patient Cloud Close Date & Time](#)

14 APR 2022 23:59

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

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 ☐

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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 APR 2022 00:01
Patient Cloud Close Date & Time	21 APR 2022 23:59

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

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 ☐

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

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

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

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

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

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

[Patient Cloud Close Date & Time](#)

05 MAY 2022 23:59

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT	DAY 607
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2022 23:59

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

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

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

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

[Patient Cloud Open Date & Time](#)

15 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

19 MAY 2022 23:59

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

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"/>

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

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

[Patient Cloud Open Date & Time](#)

22 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2022 23:59

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

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

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

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

[Patient Cloud Open Date & Time](#)

29 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2022 23:59

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

DAY 635

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

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

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

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

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

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

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

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

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	05 JUN 2022 00:01
Patient Cloud Close Date & Time	09 JUN 2022 23:59

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

DAY 642

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

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

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

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

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

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

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

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

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

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

[Patient Cloud Open Date & Time](#)

12 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

16 JUN 2022 23:59

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

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 ☐

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

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

[Patient Cloud Open Date & Time](#)

19 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2022 23:59

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

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"/>

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

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

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

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 ☐

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

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

[Patient Cloud Open Date & Time](#)

03 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

07 JUL 2022 23:59

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

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 ☐ 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 ☐

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	10 JUL 2022 00:01
Patient Cloud Close Date & Time	14 JUL 2022 23:59

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

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 ☐

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

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

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

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 ☐
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 ☐

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

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

[Patient Cloud Close Date & Time](#)

28 JUL 2022 23:59

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

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"/>

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

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

[Patient Cloud Open Date & Time](#)

31 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2022 23:59

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

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 ☐

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

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

[Patient Cloud Open Date & Time](#)

07 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2022 23:59

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

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 ☐ 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 ☐

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

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

[Patient Cloud Open Date & Time](#)

14 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

18 AUG 2022 23:59

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

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 ☐

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

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

[Patient Cloud Close Date & Time](#)

25 AUG 2022 23:59

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

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 ☐
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 ☐

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

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

[Patient Cloud Open Date & Time](#)

28 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2022 23:59

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

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"/>

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	04 SEP 2022 00:01
Patient Cloud Close Date & Time	08 SEP 2022 23:59

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

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 ☐

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

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

[Patient Cloud Open Date & Time](#)

11 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

15 SEP 2022 23:59

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

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"/>

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

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

[Patient Cloud Open Date & Time](#)

18 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

22 SEP 2022 23:59

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

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

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	25 SEP 2022 00:01
Patient Cloud Close Date & Time	29 SEP 2022 23:59

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

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 ☐

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

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

[Patient Cloud Close Date & Time](#)

06 OCT 2022 23:59

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

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 ☐

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

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

[Patient Cloud Open Date & Time](#)

09 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

13 OCT 2022 23:59

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

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

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

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

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

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 ☐

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

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

Date and time of submission	
Patient Cloud Open Date & Time	23 OCT 2022 00:01
Patient Cloud Close Date & Time	27 OCT 2022 23:59

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

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 ☐

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

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

30 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

03 NOV 2022 23:59

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

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 ☐

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

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

06 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

10 NOV 2022 23:59

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

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="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"/>

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

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

Date and time of submission	
Patient Cloud Open Date & Time	13 NOV 2022 00:01
Patient Cloud Close Date & Time	17 NOV 2022 23:59

US3212394

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 15:51:18

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		28 FEB 2021 15:07:22

US3212394

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 06 Apr 2021 15:32:32

Generated On: 09 Jun 2021 15:51:18

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 10 DEC 2020

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

Comments

If Contact Not Made, please provide Comments

US3212394

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 06 Apr 2021 15:32:32

Generated On: 09 Jun 2021 15:51:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212394

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 06 Apr 2021 15:32:31

Generated On: 09 Jun 2021 15:51:18

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 11 JAN 2021

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

Comments

If Contact Not Made, please provide Comments

US3212394

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 06 Apr 2021 15:32:31

Generated On: 09 Jun 2021 15:51:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212394

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 06 Apr 2021 15:32:31

Generated On: 09 Jun 2021 15:51:18

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 08 FEB 2021

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

Comments

If Contact Not Made, please provide Comments

US3212394

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 06 Apr 2021 15:32:31

Generated On: 09 Jun 2021 15:51:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212394

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 16 Apr 2021 19:16:25

Generated On: 09 Jun 2021 15:51:18

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3212394

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 06 Apr 2021 15:32:31

Generated On: 09 Jun 2021 15:51:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212394

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 16 Apr 2021 19:16:31

Generated On: 09 Jun 2021 15:51:18

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

Visit date (dd MMM yyyy)	09 APR 2021
--------------------------	-------------

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

Folder OID	VISIT4
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US3212394

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 16 Apr 2021 19:16:31

Generated On: 09 Jun 2021 15:51:18

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	9 APR 2021
Time of assessment (<i>00:00-23:59</i>)	14:15 (24 HR)
Vital Signs Date and Time (derived)	9 APR 2021 14:15
Temperature (<i>xxx.x</i>)	97.9 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	92 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	80 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3212394

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Apr 2021 19:16:25

Generated On: 09 Jun 2021 15:51:18

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

09 APR 2021

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

US3212394

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Apr 2021 19:16:25

Generated On: 09 Jun 2021 15:51:18

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

Collection date (dd MMM yyyy)	09 APR 2021
-------------------------------	-------------

Collection time (00:00-23:59)	14:31 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	09 APR 2021 14:31
------------------------------------	-------------------

US3212394

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 19:16:25

Generated On: 09 Jun 2021 15:51:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212394

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:51:18

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

US3212394

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:51:18

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: COVID-19 Contact

Data signed: (b) (4) 06 Apr 2021 15:32:30

Generated On: 09 Jun 2021 15:51:18

Date of Contact	25 NOV 2020
Time of Contact	13:25
Date and Time of Contact (derived)	25 NOV 2020 13:25
Type of Contact	<div>Clinic Visit - Scheduled<input type="checkbox"/></div> <div>Clinical Visit - Unscheduled<input checked="" type="checkbox"/></div> <div>Safety Call<input type="checkbox"/></div> <div>Convalescent Tele-visit<input type="checkbox"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes<input checked="" type="checkbox"/></div> <div>No<input type="checkbox"/></div>

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 06 Apr 2021 15:32:30

Generated On: 09 Jun 2021 15:51:18

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"/>

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 06 Apr 2021 15:32:30

Generated On: 09 Jun 2021 15:51:18

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	13 NOV 2020	
Assessment Not Done	False	
O2 Saturation	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 type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" 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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US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 06 Apr 2021 15:32:30

Generated On: 09 Jun 2021 15:51:18

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

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 06 Apr 2021 15:32:30

Generated On: 09 Jun 2021 15:51:18

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

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 06 Apr 2021 15:32:30

Generated On: 09 Jun 2021 15:51:18

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"/>

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 06 Apr 2021 15:32:30

Generated On: 09 Jun 2021 15:51:18

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

Date	14 NOV 2020
------	-------------

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

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

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

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

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

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

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

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

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EAB) (1725)

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 06 Apr 2021 15:32:30

Generated On: 09 Jun 2021 15:51:18

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

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 06 Apr 2021 15:32:30

Generated On: 09 Jun 2021 15:51:18

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

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 06 Apr 2021 15:32:30

Generated On: 09 Jun 2021 15:51:18

Symptom Day

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

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Form: Symptom Log (3)

Data signed: (b) (4) 06 Apr 2021 15:32:30

Generated On: 09 Jun 2021 15:51:18

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

Date	15 NOV 2020
------	-------------

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

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

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

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

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

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

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

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

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EAB) (1725)

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 06 Apr 2021 15:32:30

Generated On: 09 Jun 2021 15:51:18

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

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 06 Apr 2021 15:32:30

Generated On: 09 Jun 2021 15:51:18

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

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 06 Apr 2021 15:32:30

Generated On: 09 Jun 2021 15:51:18

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 25 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 06 Apr 2021 15:32:30

Generated On: 09 Jun 2021 15:51:18

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

Date	16 NOV 2020
------	-------------

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

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

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

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

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

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

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

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

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EAB) (1725)

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 06 Apr 2021 15:32:30

Generated On: 09 Jun 2021 15:51:18

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

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 06 Apr 2021 15:32:30

Generated On: 09 Jun 2021 15:51:18

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

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Form: Symptom Log (5)

Data signed: (b) (4) 06 Apr 2021 15:32:30

Generated On: 09 Jun 2021 15:51:18

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 25 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 06 Apr 2021 15:32:30

Generated On: 09 Jun 2021 15:51:18

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

Date	17 NOV 2020
------	-------------

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

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

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

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

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

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

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

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

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EAB) (1725)

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 06 Apr 2021 15:32:30

Generated On: 09 Jun 2021 15:51:18

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

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 06 Apr 2021 15:32:30

Generated On: 09 Jun 2021 15:51:18

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

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 06 Apr 2021 15:32:30

Generated On: 09 Jun 2021 15:51:18

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) 06 Apr 2021 15:32:30

Generated On: 09 Jun 2021 15:51:18

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

Date	18 NOV 2020
------	-------------

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

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

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

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

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

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

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

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

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 06 Apr 2021 15:32:30

Generated On: 09 Jun 2021 15:51:18

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

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 06 Apr 2021 15:32:30

Generated On: 09 Jun 2021 15:51:18

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

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 06 Apr 2021 15:32:30

Generated On: 09 Jun 2021 15:51:18

Symptom Day

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

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Form: Symptom Log (7)

Data signed: (b) (4) 06 Apr 2021 15:32:30

Generated On: 09 Jun 2021 15:51:18

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

Date	19 NOV 2020
------	-------------

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

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

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

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

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

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

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

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

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 06 Apr 2021 15:32:30

Generated On: 09 Jun 2021 15:51:18

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

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 06 Apr 2021 15:32:30

Generated On: 09 Jun 2021 15:51:18

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

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (8)

Data signed: (b) (4) 06 Apr 2021 15:32:30

Generated On: 09 Jun 2021 15:51:18

Symptom Day

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

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (8)

Data signed: (b) (4) 06 Apr 2021 15:32:30

Generated On: 09 Jun 2021 15:51:18

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

Date	20 NOV 2020
------	-------------

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

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

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

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

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

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

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

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

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EAB) (1725)

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Form: Symptom Log (8)

Data signed: (b) (4) 06 Apr 2021 15:32:30

Generated On: 09 Jun 2021 15:51:18

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (8)

Data signed: (b) (4) 06 Apr 2021 15:32:30

Generated On: 09 Jun 2021 15:51:18

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

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (9)

Data signed: (b) (4) 06 Apr 2021 15:32:30

Generated On: 09 Jun 2021 15:51:18

Symptom Day

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

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (9)

Data signed: (b) (4) 06 Apr 2021 15:32:30

Generated On: 09 Jun 2021 15:51:18

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

Date	21 NOV 2020
------	-------------

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

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

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

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

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

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

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

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

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EAB) (1725)

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (9)

Data signed: (b) (4) 06 Apr 2021 15:32:30

Generated On: 09 Jun 2021 15:51:18

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

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (9)

Data signed: (b) (4) 06 Apr 2021 15:32:30

Generated On: 09 Jun 2021 15:51:18

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

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (10)

Data signed: (b) (4) 06 Apr 2021 15:32:30

Generated On: 09 Jun 2021 15:51:18

Symptom Day

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

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (10)

Data signed: (b) (4) 06 Apr 2021 15:32:30

Generated On: 09 Jun 2021 15:51:18

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

Date	22 NOV 2020
------	-------------

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

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

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

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

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

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

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

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

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (10)

Data signed: (b) (4) 06 Apr 2021 15:32:30

Generated On: 09 Jun 2021 15:51:18

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

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EAB) (1725)

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (10)

Data signed: (b) (4) 06 Apr 2021 15:32:30

Generated On: 09 Jun 2021 15:51:18

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

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (11)

Data signed: (b) (4) 06 Apr 2021 15:32:30

Generated On: 09 Jun 2021 15:51:18

Symptom Day

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

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Form: Symptom Log (11)

Data signed: (b) (4) 06 Apr 2021 15:32:30

Generated On: 09 Jun 2021 15:51:18

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

Date	23 NOV 2020
------	-------------

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

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

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

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

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

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

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

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

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EAB) (1725)

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (11)

Data signed: (b) (4) 06 Apr 2021 15:32:30

Generated On: 09 Jun 2021 15:51:18

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

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (11)

Data signed: (b) (4) 06 Apr 2021 15:32:30

Generated On: 09 Jun 2021 15:51:18

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

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (12)

Data signed: (b) (4) 06 Apr 2021 15:32:30

Generated On: 09 Jun 2021 15:51:18

Symptom Day

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

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (12)

Data signed: (b) (4) 06 Apr 2021 15:32:30

Generated On: 09 Jun 2021 15:51:18

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

Date	24 NOV 2020
------	-------------

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

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

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

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

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

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

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

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

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Form: Symptom Log (12)

Data signed: (b) (4) 06 Apr 2021 15:32:30

Generated On: 09 Jun 2021 15:51:18

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

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (12)

Data signed: (b) (4) 06 Apr 2021 15:32:30

Generated On: 09 Jun 2021 15:51:18

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

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (13)

Data signed: (b) (4) 06 Apr 2021 15:32:30

Generated On: 09 Jun 2021 15:51:18

Symptom Day

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

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (13)

Data signed: (b) (4) 06 Apr 2021 15:32:30

Generated On: 09 Jun 2021 15:51:18

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

Date	25 NOV 2020
------	-------------

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

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

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

Temperature	98.4 F
-------------	--------

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

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

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

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

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Form: Symptom Log (13)

Data signed: (b) (4) 06 Apr 2021 15:32:30

Generated On: 09 Jun 2021 15:51:18

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

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (13)

Data signed: (b) (4) 06 Apr 2021 15:32:30

Generated On: 09 Jun 2021 15:51:18

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

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (14)

Data signed: (b) (4) 06 Apr 2021 15:32:30

Generated On: 09 Jun 2021 15:51:18

Symptom Day

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

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (14)

Data signed: (b) (4) 06 Apr 2021 15:32:30

Generated On: 09 Jun 2021 15:51:18

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	26 NOV 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	97.4 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (14)

Data signed: (b) (4) 06 Apr 2021 15:32:30

Generated On: 09 Jun 2021 15:51:18

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

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (14)

Data signed: (b) (4) 06 Apr 2021 15:32:30

Generated On: 09 Jun 2021 15:51:18

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

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (15)

Data signed: (b) (4) 06 Apr 2021 15:32:30

Generated On: 09 Jun 2021 15:51:18

Symptom Day

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

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Form: Symptom Log (15)

Data signed: (b) (4) 06 Apr 2021 15:32:30

Generated On: 09 Jun 2021 15:51:18

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

Date	27 NOV 2020
------	-------------

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

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

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

Temperature	97.6 F
-------------	--------

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

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

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

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

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (15)

Data signed: (b) (4) 06 Apr 2021 15:32:30

Generated On: 09 Jun 2021 15:51:18

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

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (15)

Data signed: (b) (4) 06 Apr 2021 15:32:30

Generated On: 09 Jun 2021 15:51:18

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

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Form: Symptom Log (16)

Data signed: (b) (4) 06 Apr 2021 15:32:30

Generated On: 09 Jun 2021 15:51:18

Symptom Day

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

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Form: Symptom Log (16)

Data signed: (b) (4) 06 Apr 2021 15:32:30

Generated On: 09 Jun 2021 15:51:18

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

Date	28 NOV 2020
------	-------------

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

O2 Saturation	100 %
---------------	-------

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

Temperature	99.5 F
-------------	--------

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

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

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

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

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (16)

Data signed: (b) (4) 06 Apr 2021 15:32:30

Generated On: 09 Jun 2021 15:51:18

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

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (16)

Data signed: (b) (4) 06 Apr 2021 15:32:30

Generated On: 09 Jun 2021 15:51:18

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

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (17)

Data signed: (b) (4) 06 Apr 2021 15:32:30

Generated On: 09 Jun 2021 15:51:18

Symptom Day

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

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (17)

Data signed: (b) (4) 06 Apr 2021 15:32:30

Generated On: 09 Jun 2021 15:51:18

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

Date	29 NOV 2020
------	-------------

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

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

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

Temperature	98.5 F
-------------	--------

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

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

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

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

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EAB) (1725)

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (17)

Data signed: (b) (4) 06 Apr 2021 15:32:30

Generated On: 09 Jun 2021 15:51:18

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

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (17)

Data signed: (b) (4) 06 Apr 2021 15:32:30

Generated On: 09 Jun 2021 15:51:18

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

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (18)

Data signed: (b) (4) 06 Apr 2021 15:32:30

Generated On: 09 Jun 2021 15:51:18

Symptom Day

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

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (18)

Data signed: (b) (4) 06 Apr 2021 15:32:30

Generated On: 09 Jun 2021 15:51:18

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

Date	30 NOV 2020
------	-------------

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

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

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

Temperature	97.9 F
-------------	--------

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

Cough	None	<input 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 25 Nov 2020

Form: Symptom Log (18)

Data signed: (b) (4) 06 Apr 2021 15:32:30

Generated On: 09 Jun 2021 15:51:18

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

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (18)

Data signed: (b) (4) 06 Apr 2021 15:32:30

Generated On: 09 Jun 2021 15:51:18

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

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (19)

Data signed: (b) (4) 06 Apr 2021 15:32:30

Generated On: 09 Jun 2021 15:51:18

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input checked="" 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 25 Nov 2020

Form: Symptom Log (19)

Data signed: (b) (4) 06 Apr 2021 15:32:30

Generated On: 09 Jun 2021 15:51:18

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

Date	01 DEC 2020
------	-------------

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

O2 Saturation	96 %
---------------	------

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

Temperature	98.0 F
-------------	--------

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

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

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

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

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (19)

Data signed: (b) (4) 06 Apr 2021 15:32:30

Generated On: 09 Jun 2021 15:51:18

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

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (19)

Data signed: (b) (4) 06 Apr 2021 15:32:30

Generated On: 09 Jun 2021 15:51:18

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

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (20)

Data signed: (b) (4) 06 Apr 2021 15:32:30

Generated On: 09 Jun 2021 15:51:18

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input checked="" 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 25 Nov 2020

Form: Symptom Log (20)

Data signed: (b) (4) 06 Apr 2021 15:32:30

Generated On: 09 Jun 2021 15:51:18

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

Date	02 DEC 2020
------	-------------

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

O2 Saturation	99 %
---------------	------

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

Temperature	97.9 F
-------------	--------

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

Cough	None	<input 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 25 Nov 2020

Form: Symptom Log (20)

Data signed: (b) (4) 06 Apr 2021 15:32:30

Generated On: 09 Jun 2021 15:51:18

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

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (20)

Data signed: (b) (4) 06 Apr 2021 15:32:30

Generated On: 09 Jun 2021 15:51:18

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

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (21)

Data signed: (b) (4) 06 Apr 2021 15:32:30

Generated On: 09 Jun 2021 15:51:18

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input checked="" 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 25 Nov 2020

Form: Symptom Log (21)

Data signed: (b) (4) 06 Apr 2021 15:32:30

Generated On: 09 Jun 2021 15:51:18

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

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

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

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

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

Temperature	98.7 F
-------------	--------

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

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

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

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

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (21)

Data signed: (b) (4) 06 Apr 2021 15:32:30

Generated On: 09 Jun 2021 15:51:18

	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"/>

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (21)

Data signed: (b) (4) 06 Apr 2021 15:32:30

Generated On: 09 Jun 2021 15:51:18

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

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 06 Apr 2021 15:32:30

Generated On: 09 Jun 2021 15:51:18

Date of Visit 25 NOV 2020

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 25 NOV 2020

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

CLIA Certified? Yes ☐
No ☐

COVID-19 Positive (CSA Programming Field Only) 0

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 06 Apr 2021 15:32:30

Generated On: 09 Jun 2021 15:51:18

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

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Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 06 Apr 2021 15:32:31

Generated On: 09 Jun 2021 15:51:18

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	27 NOV 2020
Day 5	Yes	29 NOV 2020
Day 7	Yes	01 DEC 2020
Day 9	Yes	03 DEC 2020
Day 14	NA (COVID-19 Negative)	
Day 21	NA (COVID-19 Negative)	
Day 28	NA (COVID-19 Negative)	

US3212394

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 06 Apr 2021 15:32:31

Generated On: 09 Jun 2021 15:51:18

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	25 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD1

US3212394

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 06 Apr 2021 15:32:31

Generated On: 09 Jun 2021 15:51:18

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	25 NOV 2020
Time of assessment (00:00-23:59)	13:05 (24 HR)
Vital Signs Date and Time (derived)	25 NOV 2020 13:05
Height (xxx.x)	ND - Not Done
Weight (xxx.x)	ND - Not Done
Temperature (xxx.x)	98.4 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	101 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	68 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3212394

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 06 Apr 2021 15:32:31

Generated On: 09 Jun 2021 15:51:18

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

25 NOV 2020

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

US3212394

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 06 Apr 2021 15:32:31

Generated On: 09 Jun 2021 15:51:18

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

25 NOV 2020

US3212394

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 06 Apr 2021 15:32:30

Generated On: 09 Jun 2021 15:51:18

Was this visit performed? Yes ☐
No ☒

Visit date (dd MMM yyyy)

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

Folder OID SICKD28

US3212394

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 06 Apr 2021 15:32:30

Generated On: 09 Jun 2021 15:51:18

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3212394

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 06 Apr 2021 15:32:30

Generated On: 09 Jun 2021 15:51:18

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.

US3212394

Folder: Convalescence Visit Day 28 (1)

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

Data signed: (b) (4) 06 Apr 2021 15:32:29

Generated On: 09 Jun 2021 15:51:18

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

Yes ☐

No ☐

NA (COVID-19 Negative) ☒

Date of Collection

US3212394

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

Form: Visit Date

Data signed: (b) (4) 06 Apr 2021 15:32:31

Generated On: 09 Jun 2021 15:51:18

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

Visit date (dd MMM yyyy)	8 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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US3212394

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

Form: Unblinding

Data signed: (b) (4) 22 Apr 2021 19:38:58

Generated On: 09 Jun 2021 15:51:18

Date of updated informed consent (dd MMM yyyy) 8 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) 8 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 _____

US3212394

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 06 Apr 2021 15:32:31

Generated On: 09 Jun 2021 15:51:18

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

Collection date (dd MMM yyyy)	8 JAN 2021
-------------------------------	------------

Collection time (00:00-23:59)	14:42 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	8 JAN 2021 14:42
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US3212394

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 06 Apr 2021 15:32:31

Generated On: 09 Jun 2021 15:51:18

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	8 JAN 2021
Collection time (00:00 - 23:59)	14:38
Collection Date and Time (derived)	8 JAN 2021 14:38

US3212394

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 06 Apr 2021 15:32:28

Generated On: 09 Jun 2021 15:51:18

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3212394

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 16 Apr 2021 19:16:25

Generated On: 09 Jun 2021 15:51:18

AEID

Adverse event

INJECTION SITE PAIN

Was this a medically-attended AE?

Yes ☐

No ☒

Was this a Solicited Adverse Reaction?

Yes ☒

No ☐

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

11 SEP 2020

Start time (00:00-23:59)

17:00 (24 HR)

AE start date and time (derived)

11 SEP 2020 17:00

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

19 SEP 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 16 Apr 2021 19:16:25

Generated On: 09 Jun 2021 15:51:18

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

US3212394

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 16 Apr 2021 19:16:25

Generated On: 09 Jun 2021 15:51:18

AEID

Adverse event

INJECTION SITE ERYTHEMA

Was this a medically-attended AE?

Yes ☐

No ☒

Was this a Solicited Adverse Reaction?

Yes ☒

No ☐

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

12 SEP 2020

Start time (00:00-23:59)

09:30 (24 HR)

AE start date and time (derived)

12 SEP 2020 09:30

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

18 SEP 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 16 Apr 2021 19:16:25

Generated On: 09 Jun 2021 15:51:18

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

US3212394

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 16 Apr 2021 19:16:25

Generated On: 09 Jun 2021 15:51:18

AEID

Adverse event

OTITIS MEDIA IN RIGHT EAR

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

02 NOV 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

18 NOV 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 16 Apr 2021 19:16:25

Generated On: 09 Jun 2021 15:51:18

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)	_____

US3212394

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 16 Apr 2021 19:16:25

Generated On: 09 Jun 2021 15:51:18

AEID	USA-US115-2020-MRNA-1273-P30 1000014
Adverse event	DYSYPNEA
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 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)	30 NOV 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	19 NOV 2020
Hospital Discharge Date (dd MMM yyyy)	20 NOV 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 16 Apr 2021 19:16:25

Generated On: 09 Jun 2021 15:51:18

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/>
	Related <input type="radio"/>
	Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/>
	Related <input type="radio"/>
	Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/>
	Dose Delayed <input type="radio"/>
	Investigational Product <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	

US3212394

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 16 Apr 2021 19:16:25

Generated On: 09 Jun 2021 15:51:18

SUBJECT WAS ADMITTED TO
THE HOSPITAL FOR
SHORTNESS OF BREATH ON
19NOV2020 AND DISCHARGED
20NOV2020 SUBJECT
CONFIRMED HER ADMITTANCE
LASTED FOR 24 HOURS OR
MORE. SHE WAS ADMITTED TO
HOSPITAL FOR ONE DAY
STARTING NOV. 19. SHE HAD
BLACK STOOL, BURPING AND
STOMACH ACHE STARTING
NOV12. BY NOV. 15 HER MOST
PROMINENT SYMPTOMS WERE
FATIGUE, DYSPNEA AND
TACHYCARDIA. SHE COULD
FEEL HER HEART RACING
ESPECIALLY WITH ACTIVITY.
NOV 19 SHE WAS SEEN IN THE
ER WITH TACHYCARDIA AND
DYSPNEA. HER OXYGEN
SATURATION WASN'T
SIGNIFICANTLY LOW. CT
DIDN'T SHOW ANY
PNEUMONIA OR PE. SHE WAS
STARTED ON ANTIBIOTICS FOR
POSSIBLE SMALL INFILTRATE
ON CXR. SHE SAID SHE A HAD
A LOW GRADE FEVER TO 100.7
AT THE HIGHEST. HER COVID
TESTING WAS NEGATIVE. NO
SIGNIFICANT ANEMIA. SHE
WAS DISCHARGED HOME ON
ANTIBIOTICS AND AN
INHALER. SHE FEELS MUCH
BETTER NOW. SHE STILL HAS
SOME FATIGUE. SHE HAS MILD
TACHYCARDIA WHEN SHE
WALKS. HER PULSE WAS 117
WHEN WALKING AROUND
TODAY. SHE DENIES
DIZZINESS. WILL CONTINUE TO
FOLLOW HER.

US3212394

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 16 Apr 2021 19:16:25

Generated On: 09 Jun 2021 15:51:18

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

US3212394

Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 16 Apr 2021 19:16:25

Generated On: 09 Jun 2021 15:51:18

AEID

Adverse event

TACHYCARDIA

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

15 NOV 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

30 NOV 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☐

Grade 3/Severe ☒

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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US3212394

Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 16 Apr 2021 19:16:25

Generated On: 09 Jun 2021 15:51:18

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)	_____

US3212394

Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 16 Apr 2021 19:16:25

Generated On: 09 Jun 2021 15:51:18

AEID	
Adverse event	FATIGUE
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	12 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)	30 NOV 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 16 Apr 2021 19:16:25

Generated On: 09 Jun 2021 15:51:18

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)	_____

US3212394

Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 16 Apr 2021 19:16:25

Generated On: 09 Jun 2021 15:51:18

AEID	
Adverse event	HEADACHE
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)	13 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)	23 NOV 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 16 Apr 2021 19:16:25

Generated On: 09 Jun 2021 15:51:18

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

US3212394

Folder: Adverse Events

Form: Adverse Events (9)

Data signed: (b) (4) 16 Apr 2021 19:16:25

Generated On: 09 Jun 2021 15:51:18

AEID

Adverse event

BLACK STOOL

Was this a medically-attended AE?

Yes ☐

No ☒

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

12 NOV 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

19 NOV 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (9)

Data signed: (b) (4) 16 Apr 2021 19:16:25

Generated On: 09 Jun 2021 15:51:18

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

US3212394

Folder: Adverse Events

Form: Adverse Events (10)

Data signed: (b) (4) 16 Apr 2021 19:16:25

Generated On: 09 Jun 2021 15:51:18

AEID

Adverse event

UPSET STOMACH

Was this a medically-attended AE?

Yes ☐

No ☒

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

13 NOV 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

23 NOV 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (10)

Data signed: (b) (4) 16 Apr 2021 19:16:25

Generated On: 09 Jun 2021 15:51:18

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

US3212394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 06 Apr 2021 15:32:29

Generated On: 09 Jun 2021 15:51:18

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

Yes ☒

No ☐

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

US3212394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 06 Apr 2021 15:32:28

Generated On: 09 Jun 2021 15:51:18

Name of Medication MULTIVITAMINS

Prophylaxis Yes ☒
No ☐

Indication DIETARY 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 (1)

Data signed: (b) (4) 06 Apr 2021 15:32:28

Generated On: 09 Jun 2021 15:51:18

	Intramuscular	<input 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)	UN UNK 1975	
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"/>

US3212394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 06 Apr 2021 15:32:28

Generated On: 09 Jun 2021 15:51:18

Name of Medication TYLENOL (ACETAMINOPHEN)

Prophylaxis Yes ☐
No ☒

Indication INJECTION SITE PAIN

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 06 Apr 2021 15:32:28

Generated On: 09 Jun 2021 15:51:18

	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)		15 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 15 SEP 2020		
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3212394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 06 Apr 2021 15:32:28

Generated On: 09 Jun 2021 15:51:18

Name of Medication ALEVE (NAPROXEN)

Prophylaxis Yes ☐
No ☒

Indication INJECTION SITE PAIN

Dose per administration 440

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) 06 Apr 2021 15:32:28

Generated On: 09 Jun 2021 15:51:18

	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)		15 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 15 SEP 2020		
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3212394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 06 Apr 2021 15:32:28

Generated On: 09 Jun 2021 15:51:18

Name of Medication AMOXICILLIN

Prophylaxis Yes ☐
No ☒

Indication OTITIS

Dose per administration 250

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3212394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 06 Apr 2021 15:32:28

Generated On: 09 Jun 2021 15:51:18

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	04 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)	13 NOV 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3212394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 06 Apr 2021 15:32:28

Generated On: 09 Jun 2021 15:51:18

Name of Medication LEVAQUIN

Prophylaxis Yes ☐
No ☒

Indication DYSPNEA

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 06 Apr 2021 15:32:28

Generated On: 09 Jun 2021 15:51:18

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input checked="" type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	21 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) 22 NOV 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3212394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 06 Apr 2021 15:32:28

Generated On: 09 Jun 2021 15:51:18

Name of Medication _____

Prophylaxis Yes ☐
No ☐

Indication _____

Dose per administration _____

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 ☐

US3212394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 06 Apr 2021 15:32:28

Generated On: 09 Jun 2021 15:51:18

	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) _____		
Start date completely unknown _____		
Ongoing?	Yes	<input type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input 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"/>

US3212394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 06 Apr 2021 15:32:28

Generated On: 09 Jun 2021 15:51:18

Name of Medication ZITHROMAX

Prophylaxis Yes ☐
No ☒

Indication DYSPNEA

Dose per administration 1000

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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US3212394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 06 Apr 2021 15:32:28

Generated On: 09 Jun 2021 15:51:18

	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)	25 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) 30 NOV 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3212394

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 06 Apr 2021 15:32:29

Generated On: 09 Jun 2021 15:51:18

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3212394

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 06 Apr 2021 15:32:29

Generated On: 09 Jun 2021 15:51:18

Procedure/Surgery date (<i>dd MMM</i> <i>yyyy</i>)	Procedure/Surgery	Indication	If indication is Other, specify
19 NOV 2020	CHEST CT	Adverse Event	

US3212394

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 15:51:18

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 ☐

US3212394

Folder: SAE USA-US115-2020-MRNA-1273-P301000014

Form: Safety Report Form

Data signed: (b) (4) 06 Apr 2021 15:32:31

Generated On: 09 Jun 2021 15:51:18

SAEID	USA-US115-2020-MRNA-1273-P301000014
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	VICKI
Investigator's Last Name	MILLER
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2

US3212394

Folder: SAE USA-US115-2020-MRNA-1273-P301000014

Form: Safety Report Form (1)

Data signed: (b) (4) 06 Apr 2021 15:32:31

Generated On: 09 Jun 2021 15:51:18

SAEID	USA-US115-2020-MRNA-1273-P301000014
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	VICKI
Investigator's Last Name	MILLER
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	30/NOV/2020 16:04
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

US3212394

Folder: SAE USA-US115-2020-MRNA-1273-P301000014

Form: Safety Report Form (2)

Data signed: (b) (4) 06 Apr 2021 15:32:31

Generated On: 09 Jun 2021 15:51:18

SAEID	USA-US115-2020-MRNA-1273-P301000014
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	VICKI
Investigator's Last Name	MILLER
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	10/DEC/2020 10:13
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

US3212394 (Prod: DM Clinical Research - ERN - PPDS)

US3212394

Form: Participant Creation

Generated On: 09 Jun 2021 15:51:18

[Participant ID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:36:37
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'US3212394'	RWS_ENDPOINT ENDPOINT (b) (4)	11 Sep 2020 19:54:37

US3212394

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:51:18

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:29:33
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 21:29:02
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	11 Sep 2020 20:27:26

US3212394

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:51:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:29:33
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 21:29:02
User entered '11 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	11 Sep 2020 19:54:38

US3212394

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:51:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:29:33
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 21:29:02
User entered 'Clinic (Clinic)'	Afifah Ayub (b) (4)	11 Sep 2020 20:27:26

US3212394

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:51:18

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:29:33
User entered 'SCRN'	System	11 Sep 2020 20:27:26

US3212394

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:51:18

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:29:28
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 21:29:19
User entered (b) (6) 1957'	RWS_ENDPOINT ENDPOINT (b) (4)	11 Sep 2020 19:54:39

US3212394

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:51:18

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:29:28
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 21:29:19
User entered '62'	Afifah Ayub (b) (4)	11 Sep 2020 20:28:17

US3212394

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:51:18

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:29:28
User entered 'YEARS'	System	11 Sep 2020 20:28:17

US3212394

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:51:18

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:29:28
User entered '62'	System	11 Sep 2020 20:28:40

US3212394

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:51:18

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:29:28
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 21:29:19
User entered 'Female (F)'	Afifah Ayub (b) (4)	11 Sep 2020 20:28:17

US3212394

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:51:18

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:29:28
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 21:29:19
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Afifah Ayub (b) (4)	11 Sep 2020 20:28:17

US3212394

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:51:18

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:29:28
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 21:29:19
User entered '0'	Afifah Ayub (b) (4)	11 Sep 2020 20:28:17

US3212394

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:51:18

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:29:28
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 21:29:19
User entered 'I'	Afifah Ayub (b) (4)	11 Sep 2020 20:28:17

US3212394

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:51:18

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:29:28
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 21:29:19
User entered '0'	Afifah Ayub (b) (4)	11 Sep 2020 20:28:17

US3212394

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:51:18

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:29:28
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 21:29:19
User entered '0'	Afifah Ayub (b) (4)	11 Sep 2020 20:28:17

US3212394

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:51:18

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:29:28
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 21:29:19
User entered '0'	Afifah Ayub (b) (4)	11 Sep 2020 20:28:17

US3212394

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:51:18

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:29:28
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 21:29:19
User entered '0'	Afifah Ayub (b) (4)	11 Sep 2020 20:28:17

US3212394

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:51:18

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:29:28
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 21:29:19
User entered empty.	Afifah Ayub (b) (4)	11 Sep 2020 20:28:17

US3212394

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:51:18

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:29:28
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 21:29:19
User entered '0'	Afifah Ayub (b) (4)	11 Sep 2020 20:28:17

US3212394

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:51:18

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:29:28
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 21:29:19
User entered '0'	Afifah Ayub (b) (4)	11 Sep 2020 20:28:17

US3212394

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:51:18

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:29:28
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 21:29:50
User entered '11 Sep 2020'	Afifah Ayub (b) (4)	11 Sep 2020 20:28:40

US3212394

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:51:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:29:28
User entered 'Sep 2020'	System	11 Sep 2020 20:28:40

US3212394

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:51:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:29:28
User entered '2020'	System	11 Sep 2020 20:28:40

US3212394

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:51:18

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:29:28
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 21:29:50
User entered 'Amendment 3 (3)'	Afifah Ayub (b) (4)	11 Sep 2020 20:28:40

US3212394

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:51:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:29:28
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 21:29:50
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	11 Sep 2020 20:28:40

US3212394

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:51:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:29:28
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 21:29:50
User entered empty.	Afifah Ayub (b) (4)	11 Sep 2020 20:28:40

US3212394

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:51:18

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:29:28
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 21:29:50
User entered empty.	Afifah Ayub (b) (4)	11 Sep 2020 20:28:40

US3212394

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:51:18

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:29:28
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 21:29:50
User entered 'No (N)'	Afifah Ayub (b) (4)	11 Sep 2020 20:28:40

US3212394

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:51:18

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:29:28
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 21:29:50
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	11 Sep 2020 19:54:38

US3212394

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:51:18

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:29:28
User entered 'I'	System	11 Sep 2020 20:28:46

US3212394

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 15:51:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:29:28
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 21:31:07
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	11 Sep 2020 20:28:46

US3212394

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 15:51:18

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:29:28
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 21:34:47
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	14 Sep 2020 00:19:13

US3212394

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:51:18

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:29:28
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 21:32:42
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Uterine therapeutic procedures, PT: Myomectomy, LLT: Myomectomy - version MedDRA\\23.0.	Coder Import (b) (4)	14 Sep 2020 00:20:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Sep 2020 00:20:41
Data point term sent to Coder	System	14 Sep 2020 00:20:05
User entered 'Myomectomy'	Afifah Ayub (b) (4)	14 Sep 2020 00:19:35

US3212394

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:51:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:29:28
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 21:32:43
User entered 'UN UNK 1995'	Afifah Ayub (b) (4)	14 Sep 2020 00:19:35

US3212394

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:51:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:29:28
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 21:32:45
User entered '0'	Afifah Ayub (b) (4)	14 Sep 2020 00:19:35

US3212394

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:51:18

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:29:28
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 21:32:47
User entered 'No (N)'	Afifah Ayub (b) (4)	14 Sep 2020 00:19:35

US3212394

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:51:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:29:28
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 21:32:49
User entered 'UN UNK 1995'	Afifah Ayub (b) (4)	14 Sep 2020 00:19:35

US3212394

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:51:18

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:29:28
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 21:32:50
User entered '0'	Afifah Ayub (b) (4)	14 Sep 2020 00:19:35

US3212394

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:51:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:29:28
User entered 'Jan 1995'	System	14 Sep 2020 00:19:35

US3212394

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:51:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:29:28
User entered '1995'	System	14 Sep 2020 00:19:35

US3212394

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:51:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:29:28
User entered 'Jan 1995'	System	14 Sep 2020 00:19:35

US3212394

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:51:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:29:28
User entered '1995'	System	14 Sep 2020 00:19:35

US3212394

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:51:18

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:29:28
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 21:33:04
User coded data point as SOC: Surgical and medical procedures, HLG: Obstetric and gynaecological therapeutic procedures, HLT: Obstetric therapeutic procedures, PT: Caesarean section, LLT: Cesarean section - version MedDRA\\23.0.	Coder Import (b) (4)	14 Sep 2020 00:20:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Sep 2020 00:20:41
Data point term sent to Coder	System	14 Sep 2020 00:20:05
User entered 'Cesarean Section'	Afifah Ayub (b) (4)	14 Sep 2020 00:19:50

US3212394

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:51:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:29:28
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 21:33:05
User entered 'UN UNK 1985'	Afifah Ayub (b) (4)	14 Sep 2020 00:19:50

US3212394

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:51:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:29:28
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 21:33:08
User entered '0'	Afifah Ayub (b) (4)	14 Sep 2020 00:19:50

US3212394

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:51:18

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:29:28
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 21:33:10
User entered 'No (N)'	Afifah Ayub (b) (4)	14 Sep 2020 00:19:50

US3212394

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:51:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:29:28
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 21:33:12
User entered 'UN UNK 1985'	Afifah Ayub (b) (4)	14 Sep 2020 00:19:50

US3212394

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:51:18

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:29:28
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 21:33:14
User entered '0'	Afifah Ayub (b) (4)	14 Sep 2020 00:19:50

US3212394

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:51:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:29:28
User entered 'Jan 1985'	System	14 Sep 2020 00:19:50

US3212394

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:51:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:29:28
User entered '1985'	System	14 Sep 2020 00:19:50

US3212394

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:51:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:29:28
User entered 'Jan 1985'	System	14 Sep 2020 00:19:50

US3212394

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:51:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:29:28
User entered '1985'	System	14 Sep 2020 00:19:50

US3212394

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:51:18

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:29:28
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 21:33:24
User coded data point as SOC: Surgical and medical procedures, HLGT: Gastrointestinal therapeutic procedures, HLT: Large intestine therapeutic procedures, PT: Appendectomy, LLT: Appendectomy - version MedDRA\\23.0.	Coder Import (b) (4)	14 Sep 2020 00:20:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Sep 2020 00:20:41
Data point term sent to Coder	System	14 Sep 2020 00:20:05
User entered 'Appendectomy'	Afifah Ayub (b) (4)	14 Sep 2020 00:20:04

US3212394

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:51:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:29:28
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 21:33:25
User entered 'UN UNK 1998'	Afifah Ayub (b) (4)	14 Sep 2020 00:20:04

US3212394

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:51:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:29:28
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 21:33:27
User entered '0'	Afifah Ayub (b) (4)	14 Sep 2020 00:20:04

US3212394

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:51:18

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:29:28
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 21:33:29
User entered 'No (N)'	Afifah Ayub (b) (4)	14 Sep 2020 00:20:04

US3212394

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:51:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:29:28
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 21:33:30
User entered 'UN UNK 1998'	Afifah Ayub (b) (4)	14 Sep 2020 00:20:04

US3212394

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:51:18

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:29:28
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 21:33:32
User entered '0'	Afifah Ayub (b) (4)	14 Sep 2020 00:20:04

US3212394

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:51:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:29:28
User entered 'Jan 1998'	System	14 Sep 2020 00:20:04

US3212394

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:51:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:29:28
User entered '1998'	System	14 Sep 2020 00:20:04

US3212394

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:51:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:29:28
User entered 'Jan 1998'	System	14 Sep 2020 00:20:04

US3212394

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:51:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:29:28
User entered '1998'	System	14 Sep 2020 00:20:04

US3212394

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:51:18

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:29:28
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 21:33:46
User coded data point as SOC: Infections and infestations, HLG: Infections - pathogen unspecified, HLT: Abdominal and gastrointestinal infections, PT: Appendicitis, LLT: Appendicitis - version MedDRA\\23.0.	Coder Import (b) (4)	14 Sep 2020 00:21:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Sep 2020 00:21:41
Data point term sent to Coder	System	14 Sep 2020 00:21:05
User entered 'Appendicitis'	Afifah Ayub (b) (4)	14 Sep 2020 00:20:17

US3212394

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:51:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:29:28
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 21:33:49
User entered 'UN UNK 1998'	Afifah Ayub (b) (4)	14 Sep 2020 00:20:17

US3212394

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:51:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:29:28
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 21:33:50
User entered '0'	Afifah Ayub (b) (4)	14 Sep 2020 00:20:17

US3212394

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:51:18

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:29:28
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 21:33:52
User entered 'No (N)'	Afifah Ayub (b) (4)	14 Sep 2020 00:20:17

US3212394

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:51:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:29:28
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 21:33:54
User entered 'Un UNK 1998'	Afifah Ayub (b) (4)	14 Sep 2020 00:20:17

US3212394

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:51:18

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:29:28
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 21:33:56
User entered '0'	Afifah Ayub (b) (4)	14 Sep 2020 00:20:17

US3212394

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:51:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:29:28
User entered 'Jan 1998'	System	14 Sep 2020 00:20:17

US3212394

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:51:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:29:28
User entered '1998'	System	14 Sep 2020 00:20:17

US3212394

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:51:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:29:28
User entered 'Jan 1998'	System	14 Sep 2020 00:20:17

US3212394

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:51:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:29:28
User entered '1998'	System	14 Sep 2020 00:20:17

US3212394

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:51:18

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:29:28
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 21:34:11
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Reproductive neoplasms female benign, HLT: Uterine neoplasms benign, PT: Uterine leiomyoma, LLT: Uterine fibroids - version MedDRA\\23.0.	Coder Import (b) (4)	14 Sep 2020 00:21:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Sep 2020 00:21:41
Data point term sent to Coder	System	14 Sep 2020 00:21:06
User entered 'Uterine Fibroids'	Afifah Ayub (b) (4)	14 Sep 2020 00:20:39

US3212394

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:51:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:29:28
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 21:34:14
User entered 'Un UNK 1990'	Afifah Ayub (b) (4)	14 Sep 2020 00:20:39

US3212394

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:51:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:29:28
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 21:34:17
User entered '0'	Afifah Ayub (b) (4)	14 Sep 2020 00:20:39

US3212394

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:51:18

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:29:28
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 21:34:19
User entered 'No (N)'	Afifah Ayub (b) (4)	14 Sep 2020 00:20:39

US3212394

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:51:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:29:28
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 21:34:21
User entered 'UN UNK 1995'	Afifah Ayub (b) (4)	14 Sep 2020 00:20:39

US3212394

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:51:18

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:29:28
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 21:34:22
User entered '0'	Afifah Ayub (b) (4)	14 Sep 2020 00:20:39

US3212394

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:51:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:29:28
User entered 'Jan 1990'	System	14 Sep 2020 00:20:39

US3212394

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:51:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:29:28
User entered '1990'	System	14 Sep 2020 00:20:39

US3212394

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:51:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:29:28
User entered 'Jan 1995'	System	14 Sep 2020 00:20:39

US3212394

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:51:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:29:28
User entered '1995'	System	14 Sep 2020 00:20:39

US3212394

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:51:18

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:29:28
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 21:34:30
User coded data point as SOC: Social circumstances, HLGT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\\23.0.	Coder Import (b) (4)	12 Oct 2020 18:27:20
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	12 Oct 2020 18:27:20
Data point term sent to Coder	System	12 Oct 2020 18:26:12
User entered 'Post-Menopausal'	Afifah Ayub (b) (4)	12 Oct 2020 18:25:43

US3212394

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:51:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:29:28
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 21:34:32
User entered 'UN UNK 2000'	Afifah Ayub (b) (4)	12 Oct 2020 18:25:43

US3212394

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:51:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:29:28
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 21:34:33
User entered '0'	Afifah Ayub (b) (4)	12 Oct 2020 18:25:43

US3212394

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:51:18

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:29:28
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 21:34:35
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	12 Oct 2020 18:25:43

US3212394

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:51:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:29:28
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 21:34:37
User entered empty.	Afifah Ayub (b) (4)	12 Oct 2020 18:25:43

US3212394

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:51:18

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:29:28
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 21:34:39
User entered '0'	Afifah Ayub (b) (4)	12 Oct 2020 18:25:43

US3212394

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:51:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:29:28
User entered 'Jan 2000'	System	12 Oct 2020 18:25:43

US3212394

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:51:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:29:28
User entered '2000'	System	12 Oct 2020 18:25:43

US3212394

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:51:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:29:28
User entered empty.	System	12 Oct 2020 18:25:43

US3212394

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:51:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:29:28
User entered empty.	System	12 Oct 2020 18:25:43

US3212394

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:51:18

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:29:28
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:37:30
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User closed query 'Per CDM: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 11:30:04
User coded data point as SOC: Investigations, HLGT: Cardiac and vascular investigations (excl enzyme tests), HLT: Cardiac auscultatory investigations, PT: Cardiac murmur, LLT: Heart murmur - version MedDRA\\23.0.	Coder Import (b) (4)	25 Nov 2020 21:55:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	25 Nov 2020 21:55:48
Data point term sent to Coder	System	25 Nov 2020 21:53:45
Coding entries removed.	Reagan Reed (b) (4)	25 Nov 2020 21:52:56
User entered 'Heart Murmur' reason for change: Data Entry Error	(b) (4)	25 Nov 2020 21:52:56
Query 'Per CDM: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' answered with 'no medications taken per subject. ' (Site from DM).	Reagan Reed (b) (4)	19 Nov 2020 14:03:47
User opened query 'Per CDM: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 10:48:20
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Supraventricular arrhythmias, PT: Sinus node dysfunction, LLT: Sick sinus syndrome - version MedDRA\\23.0.	Coder Import (b) (4)	11 Nov 2020 14:07:33

US3212394

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:51:18

[Condition](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by	Coder Import (b) (4)	11 Nov 2020 14:07:33
User: Coder System - version MedDRA\\23.0.	(b) (4)	
Data point term sent to Coder	System	11 Nov 2020 14:07:02
User coded data point as SOC: Cardiac disorders,	Coder Import (b) (4)	11 Nov 2020 14:06:32
HLGT: Cardiac arrhythmias, HLT: Supraventricular	(b) (4)	
arrhythmias, PT: Sinus node dysfunction, LLT: Sick		
sinus syndrome - version MedDRA\\23.0.		
User coded data point as Term Coded data point by	Coder Import (b) (4)	11 Nov 2020 14:06:32
User: Coder System - version MedDRA\\23.0.	(b) (4)	
User closed query 'DM-Coding: please split the term	System	11 Nov 2020 14:05:58
and report all the events on a separate line such as		
1) SICK SINUS SYNDROME 2) HEART		
MURMUR.' (Site from System).		
Query 'DM-Coding: please split the term and report	Reagan Reed (b) (4)	11 Nov 2020 14:05:58
all the events on a separate line such as 1) SICK	(b) (4)	
SINUS SYNDROME 2) HEART MURMUR.'		
answered with 'they are the same diagnosis. Sick		
Sinus Syndrome creates a heart murmur. Updated		
Data for DM-Coding to easier understand. ' (Site		
from System).		
Data point term sent to Coder	System	11 Nov 2020 14:05:56
User entered 'SICK SINUS SYNDROME' reason	Reagan Reed (b) (4)	11 Nov 2020 14:05:48
for change: Data Entry Error	(b) (4)	
User opened query 'DM-Coding: please split the	Coder Import (b) (4)	11 Nov 2020 13:43:30
term and report all the events on a separate line such	(b) (4)	
as 1) SICK SINUS SYNDROME 2) HEART		
MURMUR.' (Site from System).		
Data point term sent to Coder	System	23 Oct 2020 17:39:30
User entered 'Sick sinus syndrome heart murmur'	Reagan Reed (b) (4)	23 Oct 2020 17:38:59
	(b) (4)	

US3212394

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:51:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:29:28
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:37:30
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'UN UNK 2015'	Reagan Reed (b) (4)	23 Oct 2020 17:38:59

US3212394

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:51:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:29:28
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:37:30
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered '0'	Reagan Reed (b) (4)	23 Oct 2020 17:38:59

US3212394

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:51:18

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:29:28
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:37:30
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'Yes (Y)'	Reagan Reed (b) (4)	23 Oct 2020 17:38:59

US3212394

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:51:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:29:28
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:37:30
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Reagan Reed (b) (4)	23 Oct 2020 17:38:59

US3212394

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:51:18

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:29:28
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:37:30
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered '0'	Reagan Reed (b) (4)	23 Oct 2020 17:38:59

US3212394

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:51:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:29:28
User entered 'Jan 2015'	System	23 Oct 2020 17:38:59

US3212394

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:51:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:29:28
User entered '2015'	System	23 Oct 2020 17:38:59

US3212394

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:51:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:29:28
User entered empty.	System	23 Oct 2020 17:38:59

US3212394

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:51:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:29:28
User entered empty.	System	23 Oct 2020 17:38:59

US3212394

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:51:18

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:29:33
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 21:36:03
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	11 Sep 2020 20:29:27

US3212394

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:51:18

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:29:33
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 21:36:03
User entered '11 Sep 2020'	Afifah Ayub (b) (4)	11 Sep 2020 20:29:27

US3212394

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:51:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:29:33
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 21:36:03
User entered '13:50'	Afifah Ayub (b) (4)	11 Sep 2020 20:29:27

US3212394

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:51:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:29:33
User entered '11 Sep 2020 13:50'	System	11 Sep 2020 20:29:27

US3212394

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:51:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:29:33
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 21:36:03
User entered '65' in	Afifah Ayub (b) (4)	11 Sep 2020 20:29:27
DataPoint set to visible.	(b) (4) System	11 Sep 2020 20:28:46

US3212394

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:51:18

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:29:33
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 21:36:03
User entered '230.6' lb	Afifah Ayub (b) (4)	11 Sep 2020 20:29:27
DataPoint set to visible.	(b) (4) System	11 Sep 2020 20:28:46

US3212394

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:51:18

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:29:33
User entered '38.45408'	System	11 Sep 2020 20:29:27
DataPoint set to visible.	System	11 Sep 2020 20:28:46

US3212394

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:51:18

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:29:33
User entered 'kg/m2'	System	11 Sep 2020 20:29:27
DataPoint set to visible.	System	11 Sep 2020 20:28:46

US3212394

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:51:18

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:29:33
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 21:36:03
User entered missing code ND - Not Done.	Afifah Ayub (b) (4)	11 Sep 2020 20:29:27

US3212394

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:51:18

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:29:33
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 21:36:03
User entered empty; reason for change Data Entry Error	Afifah Ayub (b) (4)	07 Oct 2020 19:52:27
User entered 'Other (Other)'	Afifah Ayub (b) (4)	11 Sep 2020 20:29:27

US3212394

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:51:18

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:29:33
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 21:36:03
User entered empty; reason for change Data Entry Error	Afifah Ayub (b) (4)	07 Oct 2020 19:52:27
User entered missing code ND - Not Done.	Afifah Ayub (b) (4)	11 Sep 2020 20:29:27

US3212394

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:51:18

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:29:33
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 21:36:03
User entered missing code ND - Not Done.	Afifah Ayub (b) (4)	11 Sep 2020 20:29:27

US3212394

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:51:18

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:29:33
User entered 'bpm'	System	11 Sep 2020 20:29:27

US3212394

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:51:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:29:33
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 21:36:03
User entered missing code ND - Not Done.	Afifah Ayub (b) (4)	11 Sep 2020 20:29:27

US3212394

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:51:18

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:29:33
User entered 'breaths/min'	System	11 Sep 2020 20:29:27

US3212394

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:51:18

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:29:33
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 21:36:03
User entered missing code ND - Not Done.	Afifah Ayub (b) (4)	11 Sep 2020 20:29:27

US3212394

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:51:18

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:29:33
User entered 'mmHg'	System	11 Sep 2020 20:29:27

US3212394

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:51:18

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:29:33
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 21:36:03
User entered missing code ND - Not Done.	Afifah Ayub (b) (4)	11 Sep 2020 20:29:27

US3212394

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:51:18

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:29:33
User entered 'mmHg'	System	11 Sep 2020 20:29:27

US3212394

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:51:18

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:29:33

US3212394

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:51:18

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:29:33

US3212394

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:51:18

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:29:33
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 21:36:36
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	11 Sep 2020 20:29:33

US3212394

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:51:18

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:29:33
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 21:36:36
User entered '11 Sep 2020'	Afifah Ayub (b) (4)	11 Sep 2020 20:29:33

US3212394

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:51:18

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:29:28
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 21:37:59
User entered '11 Sep 2020'	Afifah Ayub (b) (4)	11 Sep 2020 20:29:52

US3212394

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:51:18

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:29:28
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 21:37:59
User entered 'No (N)'	Afifah Ayub (b) (4)	11 Sep 2020 20:29:52

US3212394

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:51:18

If No, what is the reason?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:29:28
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User closed query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate.' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 11:49:26
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 21:37:22
Query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate.' answered with 'updated' (Site from DM).	Afifah Ayub (b) (4)	12 Oct 2020 18:25:51
User opened query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate.' (Site from DM).	(b) (4), (b) (6)	09 Oct 2020 18:43:02
User entered 'Post-menopausal (POST-MENOPAUSAL)'	Afifah Ayub (b) (4)	11 Sep 2020 20:29:52

US3212394

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:51:18

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:29:28
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 21:37:59
User entered empty.	Afifah Ayub (b) (4)	11 Sep 2020 20:29:52

US3212394

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:51:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:29:28
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 21:37:59
User entered empty.	Afifah Ayub (b) (4)	11 Sep 2020 20:29:52

US3212394

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:51:18

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:29:28
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 21:37:59
User entered '0'	Afifah Ayub (b) (4)	11 Sep 2020 20:29:52

US3212394

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:51:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:29:28
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 21:37:59
User entered 'UN UNK 2000'	Afifah Ayub (b) (4)	11 Sep 2020 20:29:52

US3212394

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:51:18

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:29:28
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 21:37:59
User entered '0'	Afifah Ayub (b) (4)	11 Sep 2020 20:29:52

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:51:18

[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:29:33
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 21:41:38
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	11 Sep 2020 20:30:27

US3212394

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:51:18

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:29:33
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 21:41:38
User entered 'No (N)'	Afifah Ayub (b) (4)	11 Sep 2020 20:30:27

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:51:18

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)	26 Apr 2021 12:29:33
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 21:41:38
User entered 'No (N)'	Afifah Ayub (b) (4)	11 Sep 2020 20:30:27

US3212394

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:51:18

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)	26 Apr 2021 12:29:33
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 21:41:38
User entered 'No (N)'	Afifah Ayub (b) (4)	11 Sep 2020 20:30:27

US3212394

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:51:18

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:29:33
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 21:41:38
User entered 'No (N)'	Afifah Ayub (b) (4)	11 Sep 2020 20:30:27

US3212394

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:51:18

[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)	26 Apr 2021 12:29:33
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 21:41:38
User entered 'No (N)'	Afifah Ayub (b) (4)	11 Sep 2020 20:30:27

US3212394

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:51:18

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)	26 Apr 2021 12:29:33
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 21:41:38
User entered 'No (N)'	Afifah Ayub (b) (4)	11 Sep 2020 20:30:27

US3212394

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:51:18

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)	26 Apr 2021 12:29:33
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 21:41:38
User entered 'No (N)'	Afifah Ayub (b) (4)	11 Sep 2020 20:30:27

US3212394

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:51:18

[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)	26 Apr 2021 12:29:33
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 21:41:38
User entered 'No (N)'	Afifah Ayub (b) (4)	11 Sep 2020 20:30:27

US3212394

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:51:18

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)	26 Apr 2021 12:29:33
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 21:41:38
User entered 'No (N)'	Afifah Ayub (b) (4)	11 Sep 2020 20:30:27

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:51:18

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)	26 Apr 2021 12:29:33
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 21:41:38
User entered 'No (N)'	Afifah Ayub (b) (4)	11 Sep 2020 20:30:27

US3212394

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:51:18

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:29:33
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 21:41:38
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	11 Sep 2020 20:30:27

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:51:18

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:29:33
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 21:41:38
User entered 'Nurse'	Afifah Ayub (b) (4)	11 Sep 2020 20:30:27

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:51:18

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:29:33
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered '0'	Afifah Ayub (b) (4)	11 Sep 2020 20:30:27

US3212394

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:51:18

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:29:33
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 21:41:38
User entered '0'	Afifah Ayub (b) (4)	11 Sep 2020 20:30:27

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:51:18

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)	26 Apr 2021 12:29:33
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 21:41:38
User entered '0'	Afifah Ayub (b) (4)	11 Sep 2020 20:30:27

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:51:18

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)	26 Apr 2021 12:29:33
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 21:41:38
User entered 'I'	Afifah Ayub (b) (4)	11 Sep 2020 20:30:27

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:51:18

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)	26 Apr 2021 12:29:33
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 21:41:38
User entered '0'	Afifah Ayub (b) (4)	11 Sep 2020 20:30:27

US3212394

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:51:18

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:29:33
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 21:41:38
User entered '0'	Afifah Ayub (b) (4)	11 Sep 2020 20:30:27

US3212394

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:51:18

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:29:33
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'I'	Afifah Ayub (b) (4)	11 Sep 2020 20:30:27

US3212394

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:51:18

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:29:33
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 21:41:38
User entered 'Participant attended large group events in the past few weeks (e.g., wedding, places of worship, concert)'	Afifah Ayub (b) (4)	11 Sep 2020 20:30:27

US3212394

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:51:18

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 21:42:16
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	11 Sep 2020 20:30:48

US3212394

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:51:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 21:42:16
User entered '11 Sep 2020'	Afifah Ayub (b) (4)	11 Sep 2020 20:30:48

US3212394

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:51:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 21:42:16
User entered 'Clinic (Clinic)'	Afifah Ayub (b) (4)	11 Sep 2020 20:30:48

US3212394

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:51:18

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:29
User entered 'VISIT1'	System	11 Sep 2020 20:30:48

US3212394

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:51:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 21:42:39
User entered '11 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	11 Sep 2020 19:59:28

US3212394

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:51:18

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 21:42:39
User entered '113573'	RWS_ENDPOINT ENDPOINT (b) (4)	11 Sep 2020 19:59:28

US3212394

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:51:18

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 21:42:39
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4)	11 Sep 2020 19:59:28

US3212394

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:51:18

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)	25 Apr 2021 07:08:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 21:42:39
User entered 'No (N)'	Afifah Ayub (b) (4)	11 Sep 2020 20:30:56

US3212394

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:51:18

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)	25 Apr 2021 07:08:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 21:42:39
User entered 'No (N)'	Afifah Ayub (b) (4)	11 Sep 2020 20:30:56

US3212394

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:51:18

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 21:42:39
User entered 'No (N)'	Afifah Ayub (b) (4)	11 Sep 2020 20:30:56

US3212394

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:51:18

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 21:42:39
User entered 'No (N)'	Afifah Ayub (b) (4)	11 Sep 2020 20:30:56

US3212394

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:51:18

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 21:42:39
User entered 'No (N)'	Afifah Ayub (b) (4)	11 Sep 2020 20:30:56

US3212394

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:51:18

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 21:42:39
User entered 'No (N)'	Afifah Ayub (b) (4)	13 Oct 2020 15:40:24
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 06:15:59
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 06:15:58

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:51:18

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 21:42:47
User entered missing code ND - Not Done.	Afifah Ayub (b) (4)	14 Sep 2020 00:23:40

US3212394

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:51:18

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 21:42:48
User entered missing code ND - Not Done.	Afifah Ayub (b) (4)	14 Sep 2020 00:23:40

US3212394

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:51:18

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 21:42:47
User entered missing code ND - Not Done.	Afifah Ayub (b) (4)	14 Sep 2020 00:23:40

US3212394

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:51:18

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 21:42:48
User entered missing code ND - Not Done.	Afifah Ayub (b) (4)	14 Sep 2020 00:23:40

US3212394

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:51:18

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:29
User accepted default value 'Pre-Dose (PREDOSE)'	Afifah Ayub (b) (4) (b) (4)	14 Sep 2020 00:23:40

US3212394

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:51:18

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 21:43:13
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	14 Sep 2020 00:23:40

US3212394

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:51:18

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 21:43:15
User entered '11 Sep 2020'	Afifah Ayub (b) (4)	14 Sep 2020 00:23:40

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:51:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 21:43:16
User entered '13:50'	Afifah Ayub (b) (4)	14 Sep 2020 00:23:40

US3212394

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:51:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:29
User entered '11 Sep 2020 13:50'	System	14 Sep 2020 00:23:40

US3212394

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:51:18

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 21:43:46
User entered '97.5' F	Afifah Ayub (b) (4)	14 Sep 2020 00:23:40

US3212394

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:51:18

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 21:43:48
User entered 'Oral (Oral)'	Afifah Ayub (b) (4)	14 Sep 2020 00:23:40

US3212394

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:51:18

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 21:43:50
User entered empty.	Afifah Ayub (b) (4)	14 Sep 2020 00:23:40

US3212394

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:51:18

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 21:43:53
User entered '96'	Afifah Ayub (b) (4)	14 Sep 2020 00:23:40

US3212394

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:51:18

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:29
User entered 'bpm'	System	14 Sep 2020 00:23:40

US3212394

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:51:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 21:43:55
User entered '15'	Afifah Ayub (b) (4)	14 Sep 2020 00:23:40

US3212394

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:51:18

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:29
User entered 'breaths/min'	System	14 Sep 2020 00:23:40

US3212394

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:51:18

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 21:43:58
User entered '140'	Afifah Ayub (b) (4)	14 Sep 2020 00:23:40

US3212394

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:51:18

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:29
User entered 'mmHg'	System	14 Sep 2020 00:23:40

US3212394

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:51:18

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 21:43:59
User entered '78'	Afifah Ayub (b) (4)	14 Sep 2020 00:23:40

US3212394

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:51:18

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:29
User entered 'mmHg'	System	14 Sep 2020 00:23:40

US3212394

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:51:18

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 21:42:47
User entered missing code ND - Not Done.	Afifah Ayub (b) (4)	14 Sep 2020 00:23:40

US3212394

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:51:18

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 21:42:48
User entered missing code ND - Not Done.	Afifah Ayub (b) (4)	14 Sep 2020 00:23:40

US3212394

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:51:18

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:29
User accepted default value 'Post-Dose (POSTDOSE)'	Afifah Ayub (b) (4) (b) (4)	14 Sep 2020 00:23:40

US3212394

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:51:18

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 21:44:35
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	14 Sep 2020 00:23:40

US3212394

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:51:18

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 21:44:38
User entered '11 Sep 2020'	Afifah Ayub (b) (4)	14 Sep 2020 00:23:40

US3212394

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:51:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 21:44:39
User entered '17:42'	Afifah Ayub (b) (4)	14 Sep 2020 00:23:40

US3212394

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:51:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:29
User entered '11 Sep 2020 17:42'	System	14 Sep 2020 00:23:40

US3212394

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:51:18

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 21:44:43
User entered '98.3' F	Afifah Ayub (b) (4)	14 Sep 2020 00:23:40

US3212394

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:51:18

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 21:44:45
User entered 'Oral (Oral)'	Afifah Ayub (b) (4)	14 Sep 2020 00:23:40

US3212394

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:51:18

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 21:44:47
User entered empty.	Afifah Ayub (b) (4)	14 Sep 2020 00:23:40

US3212394

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:51:18

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 21:44:50
User entered '95'	Afifah Ayub (b) (4)	14 Sep 2020 00:23:40

US3212394

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:51:18

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:29
User entered 'bpm'	System	14 Sep 2020 00:23:40

US3212394

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:51:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 21:44:51
User entered '15'	Afifah Ayub (b) (4)	14 Sep 2020 00:23:40

US3212394

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:51:18

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:29
User entered 'breaths/min'	System	14 Sep 2020 00:23:40

US3212394

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:51:18

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 21:44:53
User entered '145'	Afifah Ayub (b) (4)	14 Sep 2020 00:23:40

US3212394

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:51:18

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:29
User entered 'mmHg'	System	14 Sep 2020 00:23:40

US3212394

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:51:18

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 21:44:55
User entered '85'	Afifah Ayub (b) (4)	14 Sep 2020 00:23:40

US3212394

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:51:18

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:29
User entered 'mmHg'	System	14 Sep 2020 00:23:40

US3212394

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:51:18

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 21:45:07
User entered 'No (N)'	Afifah Ayub (b) (4)	11 Sep 2020 20:31:07

US3212394

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:51:18

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 21:45:07
User entered empty.	Afifah Ayub (b) (4)	11 Sep 2020 20:31:07

US3212394

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:51:18

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 21:49:38
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	11 Sep 2020 22:03:51

US3212394

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:51:18

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 21:49:38
User entered empty.	Afifah Ayub (b) (4)	11 Sep 2020 22:03:51

US3212394

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:51:18

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)	25 Apr 2021 07:08:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 21:49:38
User entered empty.	Afifah Ayub (b) (4)	11 Sep 2020 22:03:51

US3212394

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:51:18

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:29
User entered 'MRNA-1273 OR PLACEBO'	System	11 Sep 2020 22:03:51

US3212394

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:51:18

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 21:49:38
User entered '11 Sep 2020'	Afifah Ayub (b) (4)	11 Sep 2020 22:03:51

US3212394

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:51:18

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 21:49:38
User entered '17:00'	Afifah Ayub (b) (4)	11 Sep 2020 22:03:51

US3212394

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:51:18

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:29
User entered '11 Sep 2020 17:00'	System	11 Sep 2020 22:03:51

US3212394

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:51:18

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 21:49:38
User entered 'Right Arm (RIGHT ARM)'	Afifah Ayub (b) (4)	11 Sep 2020 22:03:51

US3212394

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:51:18

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:29
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 21:49:38
User entered 'ONCE'	System	11 Sep 2020 22:03:51

US3212394

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:51:18

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:29
User entered 'INTRAMUSCULAR'	System	11 Sep 2020 22:03:51

US3212394

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:51:18

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 21:50:02
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	11 Sep 2020 20:42:06

US3212394

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:51:18

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 21:50:02
User entered '11 Sep 2020'	Afifah Ayub (b) (4)	11 Sep 2020 20:42:06

US3212394

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:51:18

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 21:50:02
User entered '15:31'	Afifah Ayub (b) (4)	11 Sep 2020 20:42:06

US3212394

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:51:18

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:29
User entered '11 Sep 2020 15:31'	System	11 Sep 2020 20:42:06

US3212394

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:51:18

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 21:50:20
User entered '11 Sep 2020'	Afifah Ayub (b) (4)	11 Sep 2020 20:31:23

US3212394

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:51:18

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:29
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Afifah Ayub (b) (4) (b) (4)	11 Sep 2020 20:31:23

US3212394

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:51:18

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 21:50:27
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	11 Sep 2020 20:31:23

US3212394

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:51:18

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 21:50:29
User entered '15:09'	Afifah Ayub (b) (4)	11 Sep 2020 20:31:23

US3212394

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:51:18

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:29
User entered '11 Sep 2020 15:09'	System	11 Sep 2020 20:31:23

US3212394

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:51:18

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:29
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Afifah Ayub (b) (4) (b) (4)	11 Sep 2020 20:31:23

US3212394

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:51:18

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 21:50:32
User entered 'No (N)'	Afifah Ayub (b) (4)	11 Sep 2020 20:31:23

US3212394

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:51:18

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 21:50:35
User entered empty.	Afifah Ayub (b) (4)	11 Sep 2020 20:31:23

US3212394

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:51:18

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:29
User entered empty.	System	11 Sep 2020 20:31:23

US3212394

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:51:18

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 21:51:08
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	11 Sep 2020 20:31:29

US3212394

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:51:18

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:29
User entered 'I'	System	11 Sep 2020 20:31:29

US3212394

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
Data entry locked.	System	11 Sep 2020 22:03:51
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Sep 2020 22:03:51

US3212394

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:51:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-09-11T17:41:36', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '423af09f-3698-456b-bfbc-e2f5f351e766'	System	11 Sep 2020 22:41:58
User entered 'Yes (Y)'	System	11 Sep 2020 22:41:58

US3212394

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:51:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-09-11T17:41:40', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '423af09f-3698-456b-bfbc-e2f5f351e766'	System	11 Sep 2020 22:41:58
User entered '98.3'	System	11 Sep 2020 22:41:58

US3212394

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:51:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-09-11T17:41:45', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '423af09f-3698-456b-bfbc-e2f5f351e766'	System	11 Sep 2020 22:41:58
User entered 'No (N)'	System	11 Sep 2020 22:41:58

US3212394

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:51:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-09-11T17:41:53', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '423af09f-3698-456b-bfbc-e2f5f351e766'	System	11 Sep 2020 22:41:58
User entered '11 Sep 2020 17:41'	System	11 Sep 2020 22:41:58

US3212394

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:51:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
User entered '11 Sep 2020 17:20'	System	11 Sep 2020 22:03:51

US3212394

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:51:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
User entered '11 Sep 2020 19:50'	System	11 Sep 2020 22:03:51

US3212394

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
Data entry locked.	System	11 Sep 2020 22:03:51
User entered 'Day 1, after vaccination (at home)'	System	11 Sep 2020 22:03:51

US3212394

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:51:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-09-12T07:31:52', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '4d25d0e9-1856-4e14-9fe0-ee7947ecee94'	System	12 Sep 2020 12:32:04
User entered 'No (N)'	System	12 Sep 2020 12:32:04

US3212394

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:51:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-09-12T07:31:56', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '4d25d0e9-1856-4e14-9fe0-ee7947ecee94'	System	12 Sep 2020 12:32:04
User entered 'No (N)'	System	12 Sep 2020 12:32:04

US3212394

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:51:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-09-12T07:32:01', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '4d25d0e9-1856-4e14-9fe0-ee7947ecee94'	System	12 Sep 2020 12:32:04
User entered '12 Sep 2020 07:32'	System	12 Sep 2020 12:32:04

US3212394

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:51:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
User entered '11 Sep 2020 20:45'	System	11 Sep 2020 22:03:51

US3212394

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:51:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
User entered '12 Sep 2020 11:59'	System	11 Sep 2020 22:03:51

US3212394

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
Data entry locked.	System	11 Sep 2020 22:03:51
User entered 'Day 2'	System	11 Sep 2020 22:03:51

US3212394

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:51:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-09-12T17:03:40', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '9951b9fe-7308-43e6-ae0c-6e68c255e303'	System	12 Sep 2020 22:04:45
User entered 'Yes (Y)'	System	12 Sep 2020 22:04:45

US3212394

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:51:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-09-12T17:04:16', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '9951b9fe-7308-43e6-ae0c-6e68c255e303'	System	12 Sep 2020 22:04:45
User entered '98.4'	System	12 Sep 2020 22:04:45

US3212394

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:51:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-09-12T17:04:35', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '9951b9fe-7308-43e6-ae0c-6e68c255e303'	System	12 Sep 2020 22:04:45
User entered 'No (N)'	System	12 Sep 2020 22:04:45

US3212394

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:51:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-09-12T17:04:42', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '9951b9fe-7308-43e6-ae0c-6e68c255e303'	System	12 Sep 2020 22:04:45
User entered '12 Sep 2020 17:04'	System	12 Sep 2020 22:04:45

US3212394

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:51:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
User entered '12 Sep 2020 12:00'	System	11 Sep 2020 22:03:51

US3212394

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:51:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
User entered '13 Sep 2020 11:59'	System	11 Sep 2020 22:03:51

US3212394

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
Data entry locked.	System	11 Sep 2020 22:03:51
User entered 'Day 3'	System	11 Sep 2020 22:03:51

US3212394

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:51:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-09-13T18:03:44', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '590d0cc1-619b-489f-bcb6-d9578a17bcc1'	System	13 Sep 2020 23:04:12
User entered 'Yes (Y)'	System	13 Sep 2020 23:04:12

US3212394

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:51:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-09-13T18:03:55', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '590d0cc1-619b-489f-bcb6-d9578a17bcc1' User entered '97.9'	System	13 Sep 2020 23:04:12
	System	13 Sep 2020 23:04:12

US3212394

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:51:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-09-13T18:04:01', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '590d0cc1-619b-489f-bcb6-d9578a17bcc1'	System	13 Sep 2020 23:04:12
User entered 'No (N)'	System	13 Sep 2020 23:04:12

US3212394

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:51:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-09-13T18:04:11', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '590d0cc1-619b-489f-bcb6-d9578a17bcc1'	System	13 Sep 2020 23:04:12
User entered '13 Sep 2020 18:04'	System	13 Sep 2020 23:04:12

US3212394

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:51:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
User entered '13 Sep 2020 12:00'	System	11 Sep 2020 22:03:51

US3212394

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:51:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
User entered '14 Sep 2020 11:59'	System	11 Sep 2020 22:03:51

US3212394

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
Data entry locked.	System	11 Sep 2020 22:03:51
User entered 'Day 4'	System	11 Sep 2020 22:03:51

US3212394

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:51:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-09-14T18:04:46', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'e61ac2c2-feeb-4065-b058-34141870a9af'	System	14 Sep 2020 23:05:04
User entered 'Yes (Y)'	System	14 Sep 2020 23:05:04

US3212394

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:51:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-09-14T18:04:51', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'e61ac2c2-feeb-4065-b058-34141870a9af'	System	14 Sep 2020 23:05:04
User entered '98.1'	System	14 Sep 2020 23:05:04

US3212394

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:51:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-09-14T18:04:54', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'e61ac2c2-feebe4065-b058-34141870a9af'	System	14 Sep 2020 23:05:04
User entered 'No (N)'	System	14 Sep 2020 23:05:04

US3212394

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:51:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-09-14T18:04:58', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'e61ac2c2-feeb-4065-b058-34141870a9af'	System	14 Sep 2020 23:05:04
User entered '14 Sep 2020 18:04'	System	14 Sep 2020 23:05:04

US3212394

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:51:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
User entered '14 Sep 2020 12:00'	System	11 Sep 2020 22:03:51

US3212394

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:51:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
User entered '15 Sep 2020 11:59'	System	11 Sep 2020 22:03:51

US3212394

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
Data entry locked.	System	11 Sep 2020 22:03:51
User entered 'Day 5'	System	11 Sep 2020 22:03:51

US3212394

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:51:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-09-15T15:17:58', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '340f25e1-61a0-41b7-8d0d-d99a8afcb1ae'	System	15 Sep 2020 20:18:36
User entered 'Yes (Y)'	System	15 Sep 2020 20:18:36

US3212394

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:51:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-09-15T15:18:02', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '340f25e1-61a0-41b7-8d0d-d99a8afcb1ae'	System	15 Sep 2020 20:18:36
User entered '97.6'	System	15 Sep 2020 20:18:36

US3212394

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:51:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-09-15T15:18:20', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '340f25e1-61a0-41b7-8d0d-d99a8afcb1ae'	System	15 Sep 2020 20:18:36
User entered 'Yes (Y)'	System	15 Sep 2020 20:18:36

US3212394

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:51:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'contacted and updated' (Site from System).	(b) (4), (b) (6)	28 Sep 2020 17:33:22
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.'	Heather Leary (b) (4)	15 Sep 2020 20:26:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-09-15T15:18:28', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '340f25e1-61a0-41b7-8d0d-d99a8afcb1ae'	(b) (4)	
User entered '1'	System	15 Sep 2020 20:18:36
	System	15 Sep 2020 20:18:36
	System	15 Sep 2020 20:18:36

US3212394

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:51:18

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-09-15T15:18:28', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '340f25e1-61a0-41b7-8d0d-d99a8afcb1ae'	System	15 Sep 2020 20:18:36
User entered '0'	System	15 Sep 2020 20:18:36

US3212394

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:51:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-09-15T15:18:33', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '340f25e1-61a0-41b7-8d0d-d99a8afcb1ae'	System	15 Sep 2020 20:18:36
User entered '15 Sep 2020 15:18'	System	15 Sep 2020 20:18:36

US3212394

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:51:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
User entered '15 Sep 2020 12:00'	System	11 Sep 2020 22:03:51

US3212394

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:51:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
User entered '16 Sep 2020 11:59'	System	11 Sep 2020 22:03:51

US3212394

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
Data entry locked.	System	11 Sep 2020 22:03:51
User entered 'Day 6'	System	11 Sep 2020 22:03:51

US3212394

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:51:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-09-16T17:06:17', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '1e7803ae-4567-443b-9b30-b96fe4e2ec56'	System	16 Sep 2020 22:07:04
User entered 'Yes (Y)'	System	16 Sep 2020 22:07:04

US3212394

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:51:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-09-16T17:06:20', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '1e7803ae-4567-443b-9b30-b96fe4e2ec56'	System	16 Sep 2020 22:07:04
User entered '98.6'	System	16 Sep 2020 22:07:04

US3212394

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:51:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-09-16T17:06:54', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '1e7803ae-4567-443b-9b30-b96fe4e2ec56'	System	16 Sep 2020 22:07:04
User entered 'No (N)'	System	16 Sep 2020 22:07:04

US3212394

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:51:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-09-16T17:06:59', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '1e7803ae-4567-443b-9b30-b96fe4e2ec56'	System	16 Sep 2020 22:07:04
User entered '16 Sep 2020 17:06'	System	16 Sep 2020 22:07:04

US3212394

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:51:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
User entered '16 Sep 2020 12:00'	System	11 Sep 2020 22:03:51

US3212394

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:51:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
User entered '17 Sep 2020 11:59'	System	11 Sep 2020 22:03:51

US3212394

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
Data entry locked.	System	11 Sep 2020 22:03:51
User entered 'Day 7'	System	11 Sep 2020 22:03:51

US3212394

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:51:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-09-17T18:04:13', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'e2cc7a17-ded4-4402-b29a-cbd6a0d7cab2'	System	17 Sep 2020 23:04:28
User entered 'Yes (Y)'	System	17 Sep 2020 23:04:28

US3212394

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:51:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-09-17T18:04:16', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'e2cc7a17-ded4-4402-b29a-cbd6a0d7cab2'	System	17 Sep 2020 23:04:28
User entered '98.6'	System	17 Sep 2020 23:04:28

US3212394

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:51:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-09-17T18:04:19', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'e2cc7a17-ded4-4402-b29a-cbd6a0d7cab2'	System	17 Sep 2020 23:04:28
User entered 'No (N)'	System	17 Sep 2020 23:04:28

US3212394

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:51:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-09-17T18:04:23', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'e2cc7a17-ded4-4402-b29a-cbd6a0d7cab2'	System	17 Sep 2020 23:04:28
User entered '17 Sep 2020 18:04'	System	17 Sep 2020 23:04:28

US3212394

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:51:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
User entered '17 Sep 2020 12:00'	System	11 Sep 2020 22:03:51

US3212394

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:51:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
User entered '18 Sep 2020 11:59'	System	11 Sep 2020 22:03:51

US3212394

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
Data entry locked.	System	11 Sep 2020 22:03:51
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Sep 2020 22:03:51

US3212394

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:51:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-09-11T17:42:04', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '56743d1c-7ea2-4f65-9865-501b231166bf'	System	11 Sep 2020 22:42:30
User entered 'None (1)'	System	11 Sep 2020 22:42:30

US3212394

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:51:18

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-09-11T17:42:08', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '56743d1c-7ea2-4f65-9865-501b231166bf'	System	11 Sep 2020 22:42:30
User entered 'No (N)'	System	11 Sep 2020 22:42:30

US3212394

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:51:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-09-11T17:42:10', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '56743d1c-7ea2-4f65-9865-501b231166bf'	System	11 Sep 2020 22:42:30
User entered 'No (N)'	System	11 Sep 2020 22:42:30

US3212394

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:51:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-09-11T17:42:14', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '56743d1c-7ea2-4f65-9865-501b231166bf'	System	11 Sep 2020 22:42:30
User entered 'None (1)'	System	11 Sep 2020 22:42:30

US3212394

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:51:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-09-11T17:42:18', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '56743d1c-7ea2-4f65-9865-501b231166bf'	System	11 Sep 2020 22:42:30
User entered '11 Sep 2020 17:42'	System	11 Sep 2020 22:42:30

US3212394

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:51:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
User entered '11 Sep 2020 17:20'	System	11 Sep 2020 22:03:51

US3212394

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:51:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
User entered '11 Sep 2020 19:50'	System	11 Sep 2020 22:03:51

US3212394

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
Data entry locked.	System	11 Sep 2020 22:03:51
User entered 'Day 1, after vaccination (at home)'	System	11 Sep 2020 22:03:51

US3212394

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:51:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-09-12T07:30:04', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'bc9396b0-fbbb-4847-970b-0613f7d129cd'	System	12 Sep 2020 12:30:48
User entered 'Does not interfere with activity (2)'	System	12 Sep 2020 12:30:48

US3212394

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:51:18

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-09-12T07:30:17', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'bc9396b0-fbbb-4847-970b-0613f7d129cd'	System	12 Sep 2020 12:30:48
User entered 'No (N)'	System	12 Sep 2020 12:30:48

US3212394

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:51:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-09-12T07:30:33', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'bc9396b0-fbbb-4847-970b-0613f7d129cd'	System	12 Sep 2020 12:30:48
User entered 'No (N)'	System	12 Sep 2020 12:30:48

US3212394

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:51:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-09-12T07:30:38', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'bc9396b0-fbbb-4847-970b-0613f7d129cd'	System	12 Sep 2020 12:30:48
User entered 'None (1)'	System	12 Sep 2020 12:30:48

US3212394

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:51:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-09-12T07:30:45', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'bc9396b0-fbbb-4847-970b-0613f7d129cd'	System	12 Sep 2020 12:30:48
User entered '12 Sep 2020 07:30'	System	12 Sep 2020 12:30:48

US3212394

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:51:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
User entered '11 Sep 2020 20:45'	System	11 Sep 2020 22:03:51

US3212394

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:51:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
User entered '12 Sep 2020 11:59'	System	11 Sep 2020 22:03:51

US3212394

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
Data entry locked.	System	11 Sep 2020 22:03:51
User entered 'Day 2'	System	11 Sep 2020 22:03:51

US3212394

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:51:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-09-12T17:04:51', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '150c557a-0fd2-4079-9628-476dc1922356'	System	12 Sep 2020 22:09:27
User entered 'Does not interfere with activity (2)'	System	12 Sep 2020 22:09:27

US3212394

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:51:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-09-12T17:04:58', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '150c557a-0fd2-4079-9628-476dc1922356'	System	12 Sep 2020 22:09:27
User entered 'Yes (Y)'	System	12 Sep 2020 22:09:27

US3212394

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:51:18

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)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-09-12T17:06:21', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '150c557a-0fd2-4079-9628-476dc1922356'	System	12 Sep 2020 22:09:27
User entered '50'	System	12 Sep 2020 22:09:27

US3212394

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:51:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-09-12T17:08:52', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '150c557a-0fd2-4079-9628-476dc1922356'	System	12 Sep 2020 22:09:27
User entered 'Yes (Y)'	System	12 Sep 2020 22:09:27

US3212394

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:51:18

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)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-09-12T17:09:00', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '150c557a-0fd2-4079-9628-476dc1922356'	System	12 Sep 2020 22:09:27
User entered '50'	System	12 Sep 2020 22:09:27

US3212394

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:51:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-09-12T17:09:18', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '150c557a-0fd2-4079-9628-476dc1922356'	System	12 Sep 2020 22:09:27
User entered 'None (1)'	System	12 Sep 2020 22:09:27

US3212394

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:51:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-09-12T17:09:25', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '150c557a-0fd2-4079-9628-476dc1922356'	System	12 Sep 2020 22:09:27
User entered '12 Sep 2020 17:09'	System	12 Sep 2020 22:09:27

US3212394

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:51:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
User entered '12 Sep 2020 12:00'	System	11 Sep 2020 22:03:51

US3212394

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:51:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
User entered '13 Sep 2020 11:59'	System	11 Sep 2020 22:03:51

US3212394

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
Data entry locked.	System	11 Sep 2020 22:03:51
User entered 'Day 3'	System	11 Sep 2020 22:03:51

US3212394

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:51:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-09-13T18:04:26', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'af29afcc-9dcd-42fa-960b-92f7e2bc60eb'	System	13 Sep 2020 23:04:59
User entered 'Does not interfere with activity (2)'	System	13 Sep 2020 23:04:59

US3212394

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:51:18

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-09-13T18:04:30', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'af29afcc-9dcd-42fa-960b-92f7e2bc60eb'	System	13 Sep 2020 23:04:59
User entered 'Yes (Y)'	System	13 Sep 2020 23:04:59

US3212394

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:51:18

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)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-09-13T18:04:43', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'af29afcc-9dcd-42fa-960b-92f7e2bc60eb'	System	13 Sep 2020 23:04:59
User entered '50'	System	13 Sep 2020 23:04:59

US3212394

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:51:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-09-13T18:04:47', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'af29afcc-9dcd-42fa-960b-92f7e2bc60eb'	System	13 Sep 2020 23:04:59
User entered 'Yes (Y)'	System	13 Sep 2020 23:04:59

US3212394

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:51:18

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)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-09-13T18:04:51', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'af29afcc-9dcd-42fa-960b-92f7e2bc60eb'	System	13 Sep 2020 23:04:59
User entered '50'	System	13 Sep 2020 23:04:59

US3212394

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:51:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-09-13T18:04:55', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'af29afcc-9dcd-42fa-960b-92f7e2bc60eb'	System	13 Sep 2020 23:04:59
User entered 'None (1)'	System	13 Sep 2020 23:04:59

US3212394

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:51:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-09-13T18:04:58', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'af29afcc-9dcd-42fa-960b-92f7e2bc60eb'	System	13 Sep 2020 23:04:59
User entered '13 Sep 2020 18:04'	System	13 Sep 2020 23:04:59

US3212394

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:51:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
User entered '13 Sep 2020 12:00'	System	11 Sep 2020 22:03:51

US3212394

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:51:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
User entered '14 Sep 2020 11:59'	System	11 Sep 2020 22:03:51

US3212394

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
Data entry locked.	System	11 Sep 2020 22:03:51
User entered 'Day 4'	System	11 Sep 2020 22:03:51

US3212394

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:51:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-09-14T18:05:06', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'f0624c6a-ab28-4105-9574-2f13eb421409'	System	14 Sep 2020 23:05:29
User entered 'Does not interfere with activity (2)'	System	14 Sep 2020 23:05:29

US3212394

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:51:18

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-09-14T18:05:10', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'f0624c6a-ab28-4105-9574-2f13eb421409'	System	14 Sep 2020 23:05:29
User entered 'Yes (Y)'	System	14 Sep 2020 23:05:29

US3212394

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:51:18

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)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-09-14T18:05:16', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'f0624c6a-ab28-4105-9574-2f13eb421409'	System	14 Sep 2020 23:05:29
User entered '50'	System	14 Sep 2020 23:05:29

US3212394

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:51:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-09-14T18:05:19', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'f0624c6a-ab28-4105-9574-2f13eb421409'	System	14 Sep 2020 23:05:29
User entered 'Yes (Y)'	System	14 Sep 2020 23:05:29

US3212394

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:51:18

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)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-09-14T18:05:22', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'f0624c6a-ab28-4105-9574-2f13eb421409'	System	14 Sep 2020 23:05:29
User entered '50'	System	14 Sep 2020 23:05:29

US3212394

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:51:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-09-14T18:05:25', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'f0624c6a-ab28-4105-9574-2f13eb421409'	System	14 Sep 2020 23:05:29
User entered 'None (1)'	System	14 Sep 2020 23:05:29

US3212394

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:51:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-09-14T18:05:27', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'f0624c6a-ab28-4105-9574-2f13eb421409'	System	14 Sep 2020 23:05:29
User entered '14 Sep 2020 18:05'	System	14 Sep 2020 23:05:29

US3212394

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:51:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
User entered '14 Sep 2020 12:00'	System	11 Sep 2020 22:03:51

US3212394

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:51:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
User entered '15 Sep 2020 11:59'	System	11 Sep 2020 22:03:51

US3212394

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
Data entry locked.	System	11 Sep 2020 22:03:51
User entered 'Day 5'	System	11 Sep 2020 22:03:51

US3212394

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:51:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-09-15T15:19:34', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '4db0c68f-18c1-45df-8521-51dc280da757'	System	15 Sep 2020 20:20:08
User entered 'Does not interfere with activity (2)'	System	15 Sep 2020 20:20:08

US3212394

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:51:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-09-15T15:19:37', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '4db0c68f-18c1-45df-8521-51dc280da757'	System	15 Sep 2020 20:20:08
User entered 'Yes (Y)'	System	15 Sep 2020 20:20:08

US3212394

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:51:18

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)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-09-15T15:19:46', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '4db0c68f-18c1-45df-8521-51dc280da757'	System	15 Sep 2020 20:20:08
User entered '50'	System	15 Sep 2020 20:20:08

US3212394

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:51:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-09-15T15:19:52', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '4db0c68f-18c1-45df-8521-51dc280da757'	System	15 Sep 2020 20:20:08
User entered 'No (N)'	System	15 Sep 2020 20:20:08

US3212394

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:51:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-09-15T15:19:58', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '4db0c68f-18c1-45df-8521-51dc280da757'	System	15 Sep 2020 20:20:08
User entered 'None (1)'	System	15 Sep 2020 20:20:08

US3212394

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:51:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-09-15T15:20:01', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '4db0c68f-18c1-45df-8521-51dc280da757'	System	15 Sep 2020 20:20:08
User entered '15 Sep 2020 15:20'	System	15 Sep 2020 20:20:08

US3212394

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:51:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
User entered '15 Sep 2020 12:00'	System	11 Sep 2020 22:03:51

US3212394

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:51:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
User entered '16 Sep 2020 11:59'	System	11 Sep 2020 22:03:51

US3212394

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
Data entry locked.	System	11 Sep 2020 22:03:51
User entered 'Day 6'	System	11 Sep 2020 22:03:51

US3212394

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:51:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-09-16T17:07:05', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'bb7b1a02-85fc-4243-a130-1a701ba93e2c'	System	16 Sep 2020 22:07:29
User entered 'Does not interfere with activity (2)'	System	16 Sep 2020 22:07:29

US3212394

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:51:18

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-09-16T17:07:08', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'bb7b1a02-85fc-4243-a130-1a701ba93e2c'	System	16 Sep 2020 22:07:29
User entered 'Yes (Y)'	System	16 Sep 2020 22:07:29

US3212394

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:51:18

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)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-09-16T17:07:13', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'bb7b1a02-85fc-4243-a130-1a701ba93e2c'	System	16 Sep 2020 22:07:29
User entered '5'	System	16 Sep 2020 22:07:29

US3212394

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:51:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-09-16T17:07:17', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'bb7b1a02-85fc-4243-a130-1a701ba93e2c'	System	16 Sep 2020 22:07:29
User entered 'No (N)'	System	16 Sep 2020 22:07:29

US3212394

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:51:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-09-16T17:07:20', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'bb7b1a02-85fc-4243-a130-1a701ba93e2c'	System	16 Sep 2020 22:07:29
User entered 'None (1)'	System	16 Sep 2020 22:07:29

US3212394

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:51:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-09-16T17:07:23', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'bb7b1a02-85fc-4243-a130-1a701ba93e2c'	System	16 Sep 2020 22:07:29
User entered '16 Sep 2020 17:07'	System	16 Sep 2020 22:07:29

US3212394

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:51:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
User entered '16 Sep 2020 12:00'	System	11 Sep 2020 22:03:51

US3212394

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:51:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
User entered '17 Sep 2020 11:59'	System	11 Sep 2020 22:03:51

US3212394

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
Data entry locked.	System	11 Sep 2020 22:03:51
User entered 'Day 7'	System	11 Sep 2020 22:03:51

US3212394

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:51:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-09-17T18:04:34', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'c7e92ae3-5215-4314-8095-1dd4d2f00a09'	System	17 Sep 2020 23:04:55
User entered 'Does not interfere with activity (2)'	System	17 Sep 2020 23:04:55

US3212394

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:51:18

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-09-17T18:04:38', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'c7e92ae3-5215-4314-8095-1dd4d2f00a09'	System	17 Sep 2020 23:04:55
User entered 'Yes (Y)'	System	17 Sep 2020 23:04:55

US3212394

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:51:18

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)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-09-17T18:04:42', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'c7e92ae3-5215-4314-8095-1dd4d2f00a09'	System	17 Sep 2020 23:04:55
User entered '5'	System	17 Sep 2020 23:04:55

US3212394

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:51:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-09-17T18:04:45', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'c7e92ae3-5215-4314-8095-1dd4d2f00a09'	System	17 Sep 2020 23:04:55
User entered 'No (N)'	System	17 Sep 2020 23:04:55

US3212394

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:51:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-09-17T18:04:48', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'c7e92ae3-5215-4314-8095-1dd4d2f00a09'	System	17 Sep 2020 23:04:55
User entered 'None (1)'	System	17 Sep 2020 23:04:55

US3212394

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:51:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-09-17T18:04:51', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'c7e92ae3-5215-4314-8095-1dd4d2f00a09'	System	17 Sep 2020 23:04:55
User entered '17 Sep 2020 18:04'	System	17 Sep 2020 23:04:55

US3212394

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:51:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
User entered '17 Sep 2020 12:00'	System	11 Sep 2020 22:03:51

US3212394

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:51:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
User entered '18 Sep 2020 11:59'	System	11 Sep 2020 22:03:51

US3212394

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
Data entry locked.	System	11 Sep 2020 22:03:51
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Sep 2020 22:03:51

US3212394

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:51:18

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-09-11T17:42:24', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '310547c1-0ab0-4aea-8f0a-57da3be984ac'	System	11 Sep 2020 22:42:55
User entered 'None (0)'	System	11 Sep 2020 22:42:55

US3212394

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:51:18

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-09-11T17:42:26', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '310547c1-0ab0-4aea-8f0a-57da3be984ac'	System	11 Sep 2020 22:42:55
User entered 'None (0)'	System	11 Sep 2020 22:42:55

US3212394

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:51:18

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-09-11T17:42:28', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '310547c1-0ab0-4aea-8f0a-57da3be984ac'	System	11 Sep 2020 22:42:55
User entered 'None (0)'	System	11 Sep 2020 22:42:55

US3212394

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:51:18

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-09-11T17:42:30', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '310547c1-0ab0-4aea-8f0a-57da3be984ac'	System	11 Sep 2020 22:42:55
User entered 'None (0)'	System	11 Sep 2020 22:42:55

US3212394

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:51:18

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-09-11T17:42:32', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '310547c1-0ab0-4aea-8f0a-57da3be984ac'	System	11 Sep 2020 22:42:55
User entered 'None (0)'	System	11 Sep 2020 22:42:55

US3212394

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:51:18

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-09-11T17:42:34', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '310547c1-0ab0-4aea-8f0a-57da3be984ac'	System	11 Sep 2020 22:42:55
User entered 'None (0)'	System	11 Sep 2020 22:42:55

US3212394

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:51:18

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)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-09-11T17:42:45', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '310547c1-0ab0-4aea-8f0a-57da3be984ac'	System	11 Sep 2020 22:42:55
User entered 'No (N)'	System	11 Sep 2020 22:42:55

US3212394

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:51:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-09-11T17:42:48', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '310547c1-0ab0-4aea-8f0a-57da3be984ac'	System	11 Sep 2020 22:42:55
User entered '11 Sep 2020 17:42'	System	11 Sep 2020 22:42:55

US3212394

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:51:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
User entered '11 Sep 2020 17:20'	System	11 Sep 2020 22:03:51

US3212394

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:51:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
User entered '11 Sep 2020 19:50'	System	11 Sep 2020 22:03:51

US3212394

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
Data entry locked.	System	11 Sep 2020 22:03:51
User entered 'Day 1, after vaccination (at home)'	System	11 Sep 2020 22:03:51

US3212394

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:51:18

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-09-12T07:31:12', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '7d2433d5-c87d-4dff-b2a5-0b447dfd1dcd'	System	12 Sep 2020 12:31:44
User entered 'No interference with activity (1)'	System	12 Sep 2020 12:31:44

US3212394

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:51:18

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-09-12T07:31:17', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '7d2433d5-c87d-4dff-b2a5-0b447dfd1dcd'	System	12 Sep 2020 12:31:44
User entered 'No interference with activity (1)'	System	12 Sep 2020 12:31:44

US3212394

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:51:18

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-09-12T07:31:24', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '7d2433d5-c87d-4dff-b2a5-0b447dfd1dcd'	System	12 Sep 2020 12:31:44
User entered 'None (0)'	System	12 Sep 2020 12:31:44

US3212394

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:51:18

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-09-12T07:31:27', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '7d2433d5-c87d-4dff-b2a5-0b447dfd1dcd'	System	12 Sep 2020 12:31:44
User entered 'None (0)'	System	12 Sep 2020 12:31:44

US3212394

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:51:18

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-09-12T07:31:29', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '7d2433d5-c87d-4dff-b2a5-0b447dfd1dcd'	System	12 Sep 2020 12:31:44
User entered 'None (0)'	System	12 Sep 2020 12:31:44

US3212394

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:51:18

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-09-12T07:31:32', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '7d2433d5-c87d-4dff-b2a5-0b447dfd1dcd'	System	12 Sep 2020 12:31:44
User entered 'None (0)'	System	12 Sep 2020 12:31:44

US3212394

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:51:18

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)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-09-12T07:31:37', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '7d2433d5-c87d-4dff-b2a5-0b447dfd1dcd'	System	12 Sep 2020 12:31:44
User entered 'No (N)'	System	12 Sep 2020 12:31:44

US3212394

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:51:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-09-12T07:31:41', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '7d2433d5-c87d-4dff-b2a5-0b447dfd1dcd'	System	12 Sep 2020 12:31:44
User entered '12 Sep 2020 07:31'	System	12 Sep 2020 12:31:44

US3212394

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:51:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
User entered '11 Sep 2020 20:45'	System	11 Sep 2020 22:03:51

US3212394

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:51:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
User entered '12 Sep 2020 11:59'	System	11 Sep 2020 22:03:51

US3212394

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
Data entry locked.	System	11 Sep 2020 22:03:51
User entered 'Day 2'	System	11 Sep 2020 22:03:51

US3212394

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:51:18

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-09-12T17:09:39', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '4c08830c-8eb2-492d-ad34-26987f3791c6'	System	12 Sep 2020 22:10:14
User entered 'None (0)'	System	12 Sep 2020 22:10:14

US3212394

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:51:18

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-09-12T17:09:44', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '4c08830c-8eb2-492d-ad34-26987f3791c6'	System	12 Sep 2020 22:10:14
User entered 'None (0)'	System	12 Sep 2020 22:10:14

US3212394

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:51:18

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-09-12T17:09:46', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '4c08830c-8eb2-492d-ad34-26987f3791c6'	System	12 Sep 2020 22:10:14
User entered 'None (0)'	System	12 Sep 2020 22:10:14

US3212394

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:51:18

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-09-12T17:09:50', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '4c08830c-8eb2-492d-ad34-26987f3791c6'	System	12 Sep 2020 22:10:14
User entered 'None (0)'	System	12 Sep 2020 22:10:14

US3212394

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:51:18

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-09-12T17:09:53', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '4c08830c-8eb2-492d-ad34-26987f3791c6'	System	12 Sep 2020 22:10:14
User entered 'None (0)'	System	12 Sep 2020 22:10:14

US3212394

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:51:18

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-09-12T17:09:59', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '4c08830c-8eb2-492d-ad34-26987f3791c6'	System	12 Sep 2020 22:10:14
User entered 'None (0)'	System	12 Sep 2020 22:10:14

US3212394

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:51:18

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)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-09-12T17:10:05', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '4c08830c-8eb2-492d-ad34-26987f3791c6'	System	12 Sep 2020 22:10:14
User entered 'No (N)'	System	12 Sep 2020 22:10:14

US3212394

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:51:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-09-12T17:10:08', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '4c08830c-8eb2-492d-ad34-26987f3791c6'	System	12 Sep 2020 22:10:14
User entered '12 Sep 2020 17:10'	System	12 Sep 2020 22:10:14

US3212394

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:51:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
User entered '12 Sep 2020 12:00'	System	11 Sep 2020 22:03:51

US3212394

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:51:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
User entered '13 Sep 2020 11:59'	System	11 Sep 2020 22:03:51

US3212394

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
Data entry locked.	System	11 Sep 2020 22:03:51
User entered 'Day 3'	System	11 Sep 2020 22:03:51

US3212394

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:51:18

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-09-13T18:05:07', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '3a883a5b-a9d6-4b4d-8378-55e9cdcff6ee'	System	13 Sep 2020 23:05:42
User entered 'None (0)'	System	13 Sep 2020 23:05:42

US3212394

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:51:18

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-09-13T18:05:11', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '3a883a5b-a9d6-4b4d-8378-55e9cdcff6ee'	System	13 Sep 2020 23:05:42
User entered 'None (0)'	System	13 Sep 2020 23:05:42

US3212394

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:51:18

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-09-13T18:05:13', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '3a883a5b-a9d6-4b4d-8378-55e9cdcff6ee'	System	13 Sep 2020 23:05:42
User entered 'None (0)'	System	13 Sep 2020 23:05:42

US3212394

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:51:18

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-09-13T18:05:16', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '3a883a5b-a9d6-4b4d-8378-55e9cdcff6ee'	System	13 Sep 2020 23:05:42
User entered 'None (0)'	System	13 Sep 2020 23:05:42

US3212394

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:51:18

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-09-13T18:05:29', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '3a883a5b-a9d6-4b4d-8378-55e9cdcff6ee'	System	13 Sep 2020 23:05:42
User entered 'None (0)'	System	13 Sep 2020 23:05:42

US3212394

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:51:18

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-09-13T18:05:31', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '3a883a5b-a9d6-4b4d-8378-55e9cdcff6ee'	System	13 Sep 2020 23:05:42
User entered 'None (0)'	System	13 Sep 2020 23:05:42

US3212394

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:51:18

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)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-09-13T18:05:38', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '3a883a5b-a9d6-4b4d-8378-55e9cdcff6ee'	System	13 Sep 2020 23:05:42
User entered 'No (N)'	System	13 Sep 2020 23:05:42

US3212394

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:51:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-09-13T18:05:40', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '3a883a5b-a9d6-4b4d-8378-55e9cdcff6ee'	System	13 Sep 2020 23:05:42
User entered '13 Sep 2020 18:05'	System	13 Sep 2020 23:05:42

US3212394

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:51:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
User entered '13 Sep 2020 12:00'	System	11 Sep 2020 22:03:51

US3212394

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:51:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
User entered '14 Sep 2020 11:59'	System	11 Sep 2020 22:03:51

US3212394

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
Data entry locked.	System	11 Sep 2020 22:03:51
User entered 'Day 4'	System	11 Sep 2020 22:03:51

US3212394

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:51:18

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-09-14T18:05:30', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '1d450403-d0f6-4d88-9958-3014013d58a9'	System	14 Sep 2020 23:05:55
User entered 'None (0)'	System	14 Sep 2020 23:05:55

US3212394

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:51:18

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-09-14T18:05:33', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '1d450403-d0f6-4d88-9958-3014013d58a9' User entered 'None (0)'	System	14 Sep 2020 23:05:55
	System	14 Sep 2020 23:05:55

US3212394

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:51:18

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-09-14T18:05:35', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '1d450403-d0f6-4d88-9958-3014013d58a9'	System	14 Sep 2020 23:05:55
User entered 'None (0)'	System	14 Sep 2020 23:05:55

US3212394

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:51:18

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-09-14T18:05:37', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '1d450403-d0f6-4d88-9958-3014013d58a9'	System	14 Sep 2020 23:05:55
User entered 'None (0)'	System	14 Sep 2020 23:05:55

US3212394

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:51:18

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-09-14T18:05:39', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '1d450403-d0f6-4d88-9958-3014013d58a9'	System	14 Sep 2020 23:05:55
User entered 'None (0)'	System	14 Sep 2020 23:05:55

US3212394

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:51:18

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-09-14T18:05:41', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '1d450403-d0f6-4d88-9958-3014013d58a9'	System	14 Sep 2020 23:05:55
User entered 'None (0)'	System	14 Sep 2020 23:05:55

US3212394

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:51:18

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)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-09-14T18:05:44', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '1d450403-d0f6-4d88-9958-3014013d58a9'	System	14 Sep 2020 23:05:55
User entered 'No (N)'	System	14 Sep 2020 23:05:55

US3212394

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:51:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-09-14T18:05:47', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '1d450403-d0f6-4d88-9958-3014013d58a9'	System	14 Sep 2020 23:05:55
User entered '14 Sep 2020 18:05'	System	14 Sep 2020 23:05:55

US3212394

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:51:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
User entered '14 Sep 2020 12:00'	System	11 Sep 2020 22:03:51

US3212394

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:51:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
User entered '15 Sep 2020 11:59'	System	11 Sep 2020 22:03:51

US3212394

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
Data entry locked.	System	11 Sep 2020 22:03:51
User entered 'Day 5'	System	11 Sep 2020 22:03:51

US3212394

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:51:18

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-09-15T15:20:07', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '0f8154ff-7df8-427c-91a0-600692c21739'	System	15 Sep 2020 20:20:41
User entered 'None (0)'	System	15 Sep 2020 20:20:41

US3212394

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:51:18

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-09-15T15:20:11', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '0f8154ff-7df8-427c-91a0-600692c21739'	System	15 Sep 2020 20:20:41
User entered 'No interference with activity (1)'	System	15 Sep 2020 20:20:41

US3212394

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:51:18

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-09-15T15:20:19', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '0f8154ff-7df8-427c-91a0-600692c21739'	System	15 Sep 2020 20:20:41
User entered 'None (0)'	System	15 Sep 2020 20:20:41

US3212394

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:51:18

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-09-15T15:20:23', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '0f8154ff-7df8-427c-91a0-600692c21739'	System	15 Sep 2020 20:20:41
User entered 'None (0)'	System	15 Sep 2020 20:20:41

US3212394

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:51:18

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-09-15T15:20:25', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '0f8154ff-7df8-427c-91a0-600692c21739'	System	15 Sep 2020 20:20:41
User entered 'None (0)'	System	15 Sep 2020 20:20:41

US3212394

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:51:18

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-09-15T15:20:27', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '0f8154ff-7df8-427c-91a0-600692c21739'	System	15 Sep 2020 20:20:41
User entered 'None (0)'	System	15 Sep 2020 20:20:41

US3212394

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:51:18

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)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-09-15T15:20:31', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '0f8154ff-7df8-427c-91a0-600692c21739'	System	15 Sep 2020 20:20:41
User entered 'No (N)'	System	15 Sep 2020 20:20:41

US3212394

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:51:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-09-15T15:20:34', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '0f8154ff-7df8-427c-91a0-600692c21739'	System	15 Sep 2020 20:20:41
User entered '15 Sep 2020 15:20'	System	15 Sep 2020 20:20:41

US3212394

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:51:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
User entered '15 Sep 2020 12:00'	System	11 Sep 2020 22:03:51

US3212394

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:51:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
User entered '16 Sep 2020 11:59'	System	11 Sep 2020 22:03:51

US3212394

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
Data entry locked.	System	11 Sep 2020 22:03:51
User entered 'Day 6'	System	11 Sep 2020 22:03:51

US3212394

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:51:18

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-09-16T17:07:29', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'fb7761a5-e03e-4b94-858e-56c83fa78746'	System	16 Sep 2020 22:08:17
User entered 'None (0)'	System	16 Sep 2020 22:08:17

US3212394

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:51:18

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-09-16T17:07:43', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'fb7761a5-e03e-4b94-858e-56c83fa78746'	System	16 Sep 2020 22:08:17
User entered 'None (0)'	System	16 Sep 2020 22:08:17

US3212394

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:51:18

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-09-16T17:07:46', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'fb7761a5-e03e-4b94-858e-56c83fa78746'	System	16 Sep 2020 22:08:17
User entered 'None (0)'	System	16 Sep 2020 22:08:17

US3212394

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:51:18

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-09-16T17:07:49', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'fb7761a5-e03e-4b94-858e-56c83fa78746'	System	16 Sep 2020 22:08:17
User entered 'None (0)'	System	16 Sep 2020 22:08:17

US3212394

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:51:18

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-09-16T17:07:51', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'fb7761a5-e03e-4b94-858e-56c83fa78746'	System	16 Sep 2020 22:08:17
User entered 'None (0)'	System	16 Sep 2020 22:08:17

US3212394

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:51:18

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-09-16T17:07:53', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'fb7761a5-e03e-4b94-858e-56c83fa78746'	System	16 Sep 2020 22:08:17
User entered 'None (0)'	System	16 Sep 2020 22:08:17

US3212394

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:51:18

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)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-09-16T17:08:08', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'fb7761a5-e03e-4b94-858e-56c83fa78746'	System	16 Sep 2020 22:08:17
User entered 'No (N)'	System	16 Sep 2020 22:08:17

US3212394

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:51:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-09-16T17:08:11', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'fb7761a5-e03e-4b94-858e-56c83fa78746'	System	16 Sep 2020 22:08:17
User entered '16 Sep 2020 17:08'	System	16 Sep 2020 22:08:17

US3212394

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:51:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
User entered '16 Sep 2020 12:00'	System	11 Sep 2020 22:03:51

US3212394

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:51:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
User entered '17 Sep 2020 11:59'	System	11 Sep 2020 22:03:51

US3212394

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
Data entry locked.	System	11 Sep 2020 22:03:51
User entered 'Day 7'	System	11 Sep 2020 22:03:51

US3212394

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:51:18

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-09-17T18:04:55', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '005a2f66-72c9-4d5c-9825-bfa26f170b3e'	System	17 Sep 2020 23:05:22
User entered 'None (0)'	System	17 Sep 2020 23:05:22

US3212394

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:51:18

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-09-17T18:05:00', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '005a2f66-72c9-4d5c-9825-bfa26f170b3e'	System	17 Sep 2020 23:05:22
User entered 'No interference with activity (1)'	System	17 Sep 2020 23:05:22

US3212394

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:51:18

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-09-17T18:05:03', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '005a2f66-72c9-4d5c-9825-bfa26f170b3e'	System	17 Sep 2020 23:05:22
User entered 'None (0)'	System	17 Sep 2020 23:05:22

US3212394

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:51:18

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-09-17T18:05:06', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '005a2f66-72c9-4d5c-9825-bfa26f170b3e'	System	17 Sep 2020 23:05:22
User entered 'None (0)'	System	17 Sep 2020 23:05:22

US3212394

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:51:18

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-09-17T18:05:08', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '005a2f66-72c9-4d5c-9825-bfa26f170b3e'	System	17 Sep 2020 23:05:22
User entered 'None (0)'	System	17 Sep 2020 23:05:22

US3212394

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:51:18

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-09-17T18:05:11', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '005a2f66-72c9-4d5c-9825-bfa26f170b3e'	System	17 Sep 2020 23:05:22
User entered 'None (0)'	System	17 Sep 2020 23:05:22

US3212394

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:51:18

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)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-09-17T18:05:16', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '005a2f66-72c9-4d5c-9825-bfa26f170b3e'	System	17 Sep 2020 23:05:22
User entered 'No (N)'	System	17 Sep 2020 23:05:22

US3212394

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:51:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-09-17T18:05:18', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '005a2f66-72c9-4d5c-9825-bfa26f170b3e'	System	17 Sep 2020 23:05:22
User entered '17 Sep 2020 18:05'	System	17 Sep 2020 23:05:22

US3212394

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:51:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
User entered '17 Sep 2020 12:00'	System	11 Sep 2020 22:03:51

US3212394

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:51:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
User entered '18 Sep 2020 11:59'	System	11 Sep 2020 22:03:51

US3212394

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(8)

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
Data entry locked.	System	16 Sep 2020 22:07:29
User entered 'Day 8'	System	16 Sep 2020 22:07:29

US3212394

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(8)

Generated On: 09 Jun 2021 15:51:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-09-18T18:46:12', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '525487e1-59b2-44e5-9ef4-90a9a921d4b8'	System	18 Sep 2020 23:46:26
User entered 'Does not interfere with activity (2)'	System	18 Sep 2020 23:46:26

US3212394

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(8)

Generated On: 09 Jun 2021 15:51:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-09-18T18:46:20', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '525487e1-59b2-44e5-9ef4-90a9a921d4b8'	System	18 Sep 2020 23:46:26
User entered '18 Sep 2020 18:46'	System	18 Sep 2020 23:46:26

US3212394

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(8)

Generated On: 09 Jun 2021 15:51:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
User entered '18 Sep 2020 12:00'	System	16 Sep 2020 22:07:29

US3212394

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(8)

Generated On: 09 Jun 2021 15:51:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
User entered '19 Sep 2020 11:59'	System	16 Sep 2020 22:07:29

US3212394

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(9)

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
Data entry locked.	System	17 Sep 2020 23:04:55
User entered 'Day 9'	System	17 Sep 2020 23:04:55

US3212394

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(9)

Generated On: 09 Jun 2021 15:51:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-09-19T12:02:07', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '1767522f-e580-42b8-8842-f2d27fe3c48a'	System	19 Sep 2020 17:02:40
User entered 'None (1)'	System	19 Sep 2020 17:02:40

US3212394

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(9)

Generated On: 09 Jun 2021 15:51:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-09-19T12:02:09', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '1767522f-e580-42b8-8842-f2d27fe3c48a'	System	19 Sep 2020 17:02:40
User entered '19 Sep 2020 12:02'	System	19 Sep 2020 17:02:40

US3212394

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(9)

Generated On: 09 Jun 2021 15:51:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
User entered '19 Sep 2020 12:00'	System	17 Sep 2020 23:04:55

US3212394

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(9)

Generated On: 09 Jun 2021 15:51:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
User entered '20 Sep 2020 11:59'	System	17 Sep 2020 23:04:55

US3212394

Folder: Diary Dose 1 (1)

Form: Redness_Day(8)

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
Data entry locked.	System	16 Sep 2020 22:07:29
User entered 'Day 8'	System	16 Sep 2020 22:07:29

US3212394

Folder: Diary Dose 1 (1)

Form: Redness_Day(8)

Generated On: 09 Jun 2021 15:51:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-09-18T18:46:38', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '5c68231c-ab09-4e35-aed5-1065a5f2b357'	System	18 Sep 2020 23:46:44
User entered 'No (N)'	System	18 Sep 2020 23:46:44

US3212394

Folder: Diary Dose 1 (1)

Form: Redness_Day(8)

Generated On: 09 Jun 2021 15:51:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-09-18T18:46:41', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '5c68231c-ab09-4e35-aed5-1065a5f2b357'	System	18 Sep 2020 23:46:44
User entered '18 Sep 2020 18:46'	System	18 Sep 2020 23:46:44

US3212394

Folder: Diary Dose 1 (1)

Form: Redness_Day(8)

Generated On: 09 Jun 2021 15:51:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
User entered '18 Sep 2020 12:00'	System	16 Sep 2020 22:07:29

US3212394

Folder: Diary Dose 1 (1)

Form: Redness_Day(8)

Generated On: 09 Jun 2021 15:51:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
User entered '19 Sep 2020 11:59'	System	16 Sep 2020 22:07:29

US3212394

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
Data entry locked.	System	17 Sep 2020 23:05:22
User entered 'Day 8'	System	17 Sep 2020 23:05:22

US3212394

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 15:51:18

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-09-18T18:46:25', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '25d75525-a649-4d44-89ac-0cb2c816267f' User entered 'None (0)'	System	18 Sep 2020 23:46:31
	System	18 Sep 2020 23:46:31

US3212394

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 15:51:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-09-18T18:46:27', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '25d75525-a649-4d44-89ac-0cb2c816267f' User entered '18 Sep 2020 18:46'	System	18 Sep 2020 23:46:31
	System	18 Sep 2020 23:46:31

US3212394

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 15:51:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
User entered '18 Sep 2020 12:00'	System	17 Sep 2020 23:05:22

US3212394

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 15:51:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
User entered '19 Sep 2020 11:59'	System	17 Sep 2020 23:05:22

US3212394

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
Data entry locked.	System	16 Sep 2020 22:07:29
User entered 'Day 8'	System	16 Sep 2020 22:07:29

US3212394

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:51:18

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)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-09-18T18:46:30', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '354e47b7-02db-43e1-8cc9-5d93b8fb8225'	System	18 Sep 2020 23:46:36
User entered 'No (N)'	System	18 Sep 2020 23:46:36

US3212394

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:51:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-09-18T18:46:32', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '354e47b7-02db-43e1-8cc9-5d93b8fb8225'	System	18 Sep 2020 23:46:36
User entered '18 Sep 2020 18:46'	System	18 Sep 2020 23:46:36

US3212394

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:51:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
User entered '18 Sep 2020 12:00'	System	16 Sep 2020 22:07:29

US3212394

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:51:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
User entered '19 Sep 2020 11:59'	System	16 Sep 2020 22:07:29

US3212394

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
Data entry locked.	System	17 Sep 2020 23:04:55
User entered 'Day 9'	System	17 Sep 2020 23:04:55

US3212394

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 15:51:18

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)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-09-19T12:02:13', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '3436923e-8238-4061-bd6d-8742f99eaab2'	System	19 Sep 2020 17:02:47
User entered 'No (N)'	System	19 Sep 2020 17:02:47

US3212394

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 15:51:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-09-19T12:02:15', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '3436923e-8238-4061-bd6d-8742f99eaab2'	System	19 Sep 2020 17:02:47
User entered '19 Sep 2020 12:02'	System	19 Sep 2020 17:02:47

US3212394

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 15:51:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
User entered '19 Sep 2020 12:00'	System	17 Sep 2020 23:04:55

US3212394

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 15:51:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
User entered '20 Sep 2020 11:59'	System	17 Sep 2020 23:04:55

US3212394

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:51:18

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:27
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	13 Oct 2020 20:42:35
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	21 Sep 2020 16:42:56

US3212394

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:51:18

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:27
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User closed query 'Per source, Day 8 Safety Call was made on 19-Sep-2020. Please verify with source and update EDC accordingly.' (Site from CRA).	(b) (4), (b) (6)	23 Oct 2020 20:19:21
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 20:19:18
Query 'Per source, Day 8 Safety Call was made on 19-Sep-2020. Please verify with source and update EDC accordingly.' answered with 'updated' (Site from CRA).	Afifah Ayub (b) (4)	13 Oct 2020 21:18:07
User entered '19 Sep 2020' reason for change: Data Entry Error	Afifah Ayub (b) (4)	13 Oct 2020 21:18:02
User opened query 'Per source, Day 8 Safety Call was made on 19-Sep-2020. Please verify with source and update EDC accordingly.' (Site from CRA).	(b) (4), (b) (6)	13 Oct 2020 20:42:25
User entered '18 Sep 2020'	Laura Ngansop Djampou (b) (4)	21 Sep 2020 16:42:56

US3212394

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:51:18

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:27
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	13 Oct 2020 20:42:38
User entered 'Contact Made (CONTACT MADE)'	Laura Ngansop Djampou (b) (4)	21 Sep 2020 16:42:56

US3212394

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:51:18

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:27
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	13 Oct 2020 20:42:40
User entered empty.	Laura Ngansop Djampou (b) (4)	21 Sep 2020 16:42:56

US3212394

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:51:18

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:27
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	13 Oct 2020 20:42:59
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	21 Sep 2020 16:43:05

US3212394

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:51:18

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:27
User entered 'I'	System	21 Sep 2020 16:43:05

US3212394

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:51:18

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:27
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	13 Oct 2020 20:43:21
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	28 Sep 2020 14:59:41

US3212394

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:51:18

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:27
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	13 Oct 2020 20:43:21
User entered '25 Sep 2020'	Laura Ngansop Djampou (b) (4)	28 Sep 2020 14:59:41

US3212394

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:51:18

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:27
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	13 Oct 2020 20:43:21
User entered 'Contact Made (CONTACT MADE)'	Laura Ngansop Djampou (b) (4)	28 Sep 2020 14:59:41

US3212394

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:51:18

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:27
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	13 Oct 2020 20:43:21
User entered empty.	Laura Ngansop Djampou (b) (4)	28 Sep 2020 14:59:41

US3212394

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:51:18

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:27
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	13 Oct 2020 20:43:47
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	28 Sep 2020 14:59:46

US3212394

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:51:18

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:27
User entered 'I'	System	28 Sep 2020 14:59:46

US3212394

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:51:18

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:27
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	13 Oct 2020 20:44:24
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	12 Oct 2020 15:21:43

US3212394

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:51:18

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:27
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:37:52
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Un-verified.	Laura Ngansop Djampou (b) (4)	07 Dec 2020 20:12:50
User entered '02 Oct 2020' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	07 Dec 2020 20:12:50
DataPoint Verified.	(b) (4), (b) (6)	13 Oct 2020 20:44:24
User entered '2 Oct 2020'	Laura Ngansop Djampou (b) (4)	12 Oct 2020 15:21:43

US3212394

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:51:18

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:27
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	13 Oct 2020 20:44:24
User entered 'Contact Made (CONTACT MADE)'	Laura Ngansop Djampou (b) (4)	12 Oct 2020 15:21:43

US3212394

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:51:18

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:27
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	13 Oct 2020 20:44:24
User entered empty.	Laura Ngansop Djampou (b) (4)	12 Oct 2020 15:21:43

US3212394

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:51:18

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:27
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	13 Oct 2020 20:45:15
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	12 Oct 2020 15:21:47

US3212394

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:51:18

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:27
User entered 'I'	System	12 Oct 2020 15:21:47

US3212394

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:51:18

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:41:23
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	12 Oct 2020 16:26:36

US3212394

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:51:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:41:23
User entered '12 Oct 2020'	Laura Ngansop Djampou (b) (4)	12 Oct 2020 16:26:36

US3212394

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:51:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:41:23
User entered 'Clinic (Clinic)'	Laura Ngansop Djampou (b) (4)	12 Oct 2020 16:26:36

US3212394

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:51:18

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:29
User entered 'VISIT2'	System	12 Oct 2020 16:26:36

US3212394

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:51:18

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:29
User accepted default value 'Pre-Dose (PREDOSE)'	Laura Ngansop Djampou (b) (4)	12 Oct 2020 16:27:32

US3212394

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:51:18

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:42
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	12 Oct 2020 16:27:32

US3212394

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:51:18

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:45
User entered '12 Oct 2020'	Laura Ngansop Djampou (b) (4)	12 Oct 2020 16:27:32

US3212394

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:51:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:47
User entered '09:10'	Laura Ngansop Djampou (b) (4)	12 Oct 2020 16:27:32

US3212394

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:51:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:29
User entered '12 Oct 2020 09:10'	System	12 Oct 2020 16:27:32

US3212394

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:51:18

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:52
User entered '97.5' F	Laura Ngansop Djampou (b) (4)	12 Oct 2020 16:27:32

US3212394

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:51:18

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:54
User entered 'Oral (Oral)'	Laura Ngansop Djampou (b) (4)	12 Oct 2020 16:27:32

US3212394

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:51:18

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:55
User entered empty.	Laura Ngansop Djampou (b) (4)	12 Oct 2020 16:27:32

US3212394

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:51:18

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:58
User entered '95'	Laura Ngansop Djampou (b) (4)	12 Oct 2020 16:27:32

US3212394

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:51:18

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:29
User entered 'bpm'	System	12 Oct 2020 16:27:32

US3212394

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:51:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:44:02
User entered '16'	Laura Ngansop Djampou (b) (4)	12 Oct 2020 16:27:32

US3212394

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:51:18

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:29
User entered 'breaths/min'	System	12 Oct 2020 16:27:32

US3212394

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:51:18

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:44:04
User entered '108'	Laura Ngansop Djampou (b) (4)	12 Oct 2020 16:27:32

US3212394

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:51:18

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:29
User entered 'mmHg'	System	12 Oct 2020 16:27:32

US3212394

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:51:18

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:44:06
User entered '79'	Laura Ngansop Djampou (b) (4)	12 Oct 2020 16:27:32

US3212394

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:51:18

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:29
User entered 'mmHg'	System	12 Oct 2020 16:27:32

US3212394

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:51:18

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:29
User accepted default value 'Post-Dose (POSTDOSE)'	Laura Ngansop Djampou (b) (4)	12 Oct 2020 16:31:19

US3212394

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:51:18

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:44:31
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	12 Oct 2020 16:31:19

US3212394

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:51:18

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:44:31
User entered '12 Oct 2020'	Laura Ngansop Djampou (b) (4)	12 Oct 2020 16:31:19

US3212394

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:51:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:44:31
User entered '11:00'	Laura Ngansop Djampou (b) (4)	12 Oct 2020 16:31:19

US3212394

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:51:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:29
User entered '12 Oct 2020 11:00'	System	12 Oct 2020 16:31:19

US3212394

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:51:18

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:44:31
User closed query 'Temperature reported is out of range >41.7C (107F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	12 Oct 2020 16:32:15
Query 'Temperature reported is out of range >41.7C (107F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered by data change (Site from System).	System	12 Oct 2020 16:32:15
User entered '98.1' F reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	12 Oct 2020 16:32:15
User opened query 'Temperature reported is out of range >41.7C (107F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	12 Oct 2020 16:31:19
User entered '108' F	Laura Ngansop Djampou (b) (4)	12 Oct 2020 16:31:19

US3212394

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:51:18

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:44:31
User entered 'Oral (Oral)'	Laura Ngansop Djampou (b) (4)	12 Oct 2020 16:31:19

US3212394

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:51:18

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:44:31
User entered empty.	Laura Ngansop Djampou (b) (4)	12 Oct 2020 16:31:19

US3212394

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:51:18

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:44:31
User entered '97'	Laura Ngansop Djampou (b) (4)	12 Oct 2020 16:31:19

US3212394

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:51:18

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:29
User entered 'bpm'	System	12 Oct 2020 16:31:19

US3212394

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:51:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:44:31
User entered '16'	Laura Ngansop Djampou (b) (4)	12 Oct 2020 16:31:19

US3212394

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:51:18

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:29
User entered 'breaths/min'	System	12 Oct 2020 16:31:19

US3212394

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:51:18

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:44:31
User entered '108'	Laura Ngansop Djampou (b) (4)	12 Oct 2020 16:31:19

US3212394

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:51:18

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:29
User entered 'mmHg'	System	12 Oct 2020 16:31:19

US3212394

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:51:18

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:44:31
User entered '66'	Laura Ngansop Djampou (b) (4)	12 Oct 2020 16:31:19

US3212394

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:51:18

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:29
User entered 'mmHg'	System	12 Oct 2020 16:31:19

US3212394

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:51:18

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:44:52
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	12 Oct 2020 16:32:35

US3212394

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:51:18

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:44:52
User entered '12 Oct 2020'	Laura Ngansop Djampou (b) (4)	12 Oct 2020 16:32:35

US3212394

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:51:18

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:15:17
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	12 Oct 2020 15:31:25

US3212394

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:51:18

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:15:17
User entered empty.	Afifah Ayub (b) (4)	12 Oct 2020 15:31:25

US3212394

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:51:18

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)	25 Apr 2021 07:08:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:15:17
User entered empty.	Afifah Ayub (b) (4)	12 Oct 2020 15:31:25

US3212394

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:51:18

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:29
User entered 'MRNA-1273 OR PLACEBO'	System	12 Oct 2020 15:31:25

US3212394

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:51:18

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:15:17
User entered '12 Oct 2020'	Afifah Ayub (b) (4)	12 Oct 2020 15:31:25

US3212394

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:51:18

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:15:17
User entered '10:25'	Afifah Ayub (b) (4)	12 Oct 2020 15:31:25

US3212394

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:51:18

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:29
User entered '12 Oct 2020 10:25'	System	12 Oct 2020 15:31:25

US3212394

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:51:18

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:15:17
User closed query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' (Site from System).	System	12 Oct 2020 15:31:30
Query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' answered by data change (Site from System).	System	12 Oct 2020 15:31:30
User entered 'Right Arm (RIGHT ARM)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	12 Oct 2020 15:31:30
User opened query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' (Site from System).	System	12 Oct 2020 15:31:25
User entered 'Left Arm (LEFT ARM)'	Afifah Ayub (b) (4)	12 Oct 2020 15:31:25

US3212394

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:51:18

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:29
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:15:17
User entered 'ONCE'	System	12 Oct 2020 15:31:25

US3212394

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:51:18

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:29
User entered 'INTRAMUSCULAR'	System	12 Oct 2020 15:31:25

US3212394

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:51:18

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:57:57
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	12 Oct 2020 16:32:49

US3212394

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:51:18

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:57:57
User entered '12 Oct 2020'	Laura Ngansop Djampou (b) (4)	12 Oct 2020 16:32:49

US3212394

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:51:18

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:57:57
User entered '10:11'	Laura Ngansop Djampou (b) (4)	12 Oct 2020 16:32:49

US3212394

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:51:18

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:29
User entered '12 Oct 2020 10:11'	System	12 Oct 2020 16:32:49

US3212394

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:51:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:58:14
User entered '12 Oct 2020'	Laura Ngansop Djampou (b) (4)	12 Oct 2020 16:33:57

US3212394

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:51:18

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:29
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Laura Ngansop Djampou (b) (4)	12 Oct 2020 16:33:57

US3212394

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:51:18

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:58:14
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	12 Oct 2020 16:33:57

US3212394

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:51:18

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:58:14
User entered '10:05'	Laura Ngansop Djampou (b) (4)	12 Oct 2020 16:33:57

US3212394

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:51:18

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:29
User entered '12 Oct 2020 10:05'	System	12 Oct 2020 16:33:57

US3212394

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:51:18

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:29
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Laura Ngansop Djampou (b) (4)	12 Oct 2020 16:33:57

US3212394

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:51:18

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:58:14
User entered 'No (N)'	Laura Ngansop Djampou (b) (4)	12 Oct 2020 16:33:57

US3212394

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:51:18

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:58:14
User entered empty.	Laura Ngansop Djampou (b) (4)	12 Oct 2020 16:33:57

US3212394

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:51:18

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:29
User entered empty.	System	12 Oct 2020 16:33:57

US3212394

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:51:18

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:58:30
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	12 Oct 2020 16:34:04

US3212394

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:51:18

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:29
User entered 'I'	System	12 Oct 2020 16:34:04

US3212394

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
Data entry locked.	System	12 Oct 2020 15:31:25
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	12 Oct 2020 15:31:25

US3212394

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:51:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-10-12T11:01:09', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '35fae3e2-4019-42ba-83c8-a143a4c529be'	System	12 Oct 2020 16:01:42
User entered 'Yes (Y)'	System	12 Oct 2020 16:01:42

US3212394

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:51:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-10-12T11:01:14', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '35fae3e2-4019-42ba-83c8-a143a4c529be'	System	12 Oct 2020 16:01:42
User entered '98.1'	System	12 Oct 2020 16:01:42

US3212394

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:51:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-10-12T11:01:19', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '35fae3e2-4019-42ba-83c8-a143a4c529be'	System	12 Oct 2020 16:01:42
User entered 'No (N)'	System	12 Oct 2020 16:01:42

US3212394

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:51:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-10-12T11:01:25', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '35fae3e2-4019-42ba-83c8-a143a4c529be'	System	12 Oct 2020 16:01:42
User entered '12 Oct 2020 11:01'	System	12 Oct 2020 16:01:42

US3212394

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:51:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
User entered '12 Oct 2020 10:45'	System	12 Oct 2020 15:31:25

US3212394

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:51:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
User entered '12 Oct 2020 13:15'	System	12 Oct 2020 15:31:25

US3212394

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
Data entry locked.	System	12 Oct 2020 15:31:25
User entered 'Day 1, after vaccination (at home)'	System	12 Oct 2020 15:31:25

US3212394

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:51:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-10-12T20:33:42', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '7306da83-b4c4-4293-b8ec-6826626d6d52'	System	13 Oct 2020 01:34:16
User entered 'Yes (Y)'	System	13 Oct 2020 01:34:16

US3212394

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:51:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-10-12T20:33:46', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '7306da83-b4c4-4293-b8ec-6826626d6d52'	System	13 Oct 2020 01:34:16
User entered '99.5'	System	13 Oct 2020 01:34:16

US3212394

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:51:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-10-12T20:33:53', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '7306da83-b4c4-4293-b8ec-6826626d6d52'	System	13 Oct 2020 01:34:16
User entered 'No (N)'	System	13 Oct 2020 01:34:16

US3212394

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:51:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-10-12T20:34:09', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '7306da83-b4c4-4293-b8ec-6826626d6d52'	System	13 Oct 2020 01:34:16
User entered '12 Oct 2020 20:34'	System	13 Oct 2020 01:34:16

US3212394

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:51:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
User entered '12 Oct 2020 14:10'	System	12 Oct 2020 15:31:25

US3212394

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:51:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
User entered '13 Oct 2020 11:59'	System	12 Oct 2020 15:31:25

US3212394

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
Data entry locked.	System	12 Oct 2020 15:31:25
User entered 'Day 2'	System	12 Oct 2020 15:31:25

US3212394

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:51:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-10-13T16:57:14', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'a72afd38-8803-4420-a4e5-56ce1f49f950'	System	13 Oct 2020 21:57:32
User entered 'Yes (Y)'	System	13 Oct 2020 21:57:32

US3212394

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:51:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-10-13T16:57:20', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'a72afd38-8803-4420-a4e5-56ce1f49f950'	System	13 Oct 2020 21:57:32
User entered '98.7'	System	13 Oct 2020 21:57:32

US3212394

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:51:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-10-13T16:57:23', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'a72afd38-8803-4420-a4e5-56ce1f49f950'	System	13 Oct 2020 21:57:32
User entered 'No (N)'	System	13 Oct 2020 21:57:32

US3212394

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:51:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-10-13T16:57:29', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'a72afd38-8803-4420-a4e5-56ce1f49f950'	System	13 Oct 2020 21:57:32
User entered '13 Oct 2020 16:57'	System	13 Oct 2020 21:57:32

US3212394

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:51:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
User entered '13 Oct 2020 12:00'	System	12 Oct 2020 15:31:25

US3212394

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:51:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
User entered '14 Oct 2020 11:59'	System	12 Oct 2020 15:31:25

US3212394

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
Data entry locked.	System	12 Oct 2020 15:31:25
User entered 'Day 3'	System	12 Oct 2020 15:31:25

US3212394

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:51:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-10-14T17:31:54', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'e6efc8c7-84e7-463c-ad0d-481828585c68'	System	14 Oct 2020 22:32:22
User entered 'Yes (Y)'	System	14 Oct 2020 22:32:22

US3212394

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:51:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-10-14T17:32:06', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'e6efc8c7-84e7-463c-ad0d-481828585c68'	System	14 Oct 2020 22:32:22
User entered '98.9'	System	14 Oct 2020 22:32:22

US3212394

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:51:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-10-14T17:32:13', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'e6efc8c7-84e7-463c-ad0d-481828585c68'	System	14 Oct 2020 22:32:22
User entered 'No (N)'	System	14 Oct 2020 22:32:22

US3212394

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:51:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-10-14T17:32:17', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'e6efc8c7-84e7-463c-ad0d-481828585c68'	System	14 Oct 2020 22:32:22
User entered '14 Oct 2020 17:32'	System	14 Oct 2020 22:32:22

US3212394

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:51:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
User entered '14 Oct 2020 12:00'	System	12 Oct 2020 15:31:25

US3212394

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:51:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
User entered '15 Oct 2020 11:59'	System	12 Oct 2020 15:31:25

US3212394

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
Data entry locked.	System	12 Oct 2020 15:31:25
User entered 'Day 4'	System	12 Oct 2020 15:31:25

US3212394

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:51:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-10-15T17:48:14', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '57ef5598-f719-4d91-9b79-f2908dd99283'	System	15 Oct 2020 22:48:29
User entered 'Yes (Y)'	System	15 Oct 2020 22:48:29

US3212394

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:51:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-10-15T17:48:18', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '57ef5598-f719-4d91-9b79-f2908dd99283'	System	15 Oct 2020 22:48:29
User entered '98.6'	System	15 Oct 2020 22:48:29

US3212394

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:51:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-10-15T17:48:21', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '57ef5598-f719-4d91-9b79-f2908dd99283'	System	15 Oct 2020 22:48:29
User entered 'No (N)'	System	15 Oct 2020 22:48:29

US3212394

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:51:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-10-15T17:48:24', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '57ef5598-f719-4d91-9b79-f2908dd99283'	System	15 Oct 2020 22:48:29
User entered '15 Oct 2020 17:48'	System	15 Oct 2020 22:48:29

US3212394

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:51:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
User entered '15 Oct 2020 12:00'	System	12 Oct 2020 15:31:25

US3212394

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:51:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
User entered '16 Oct 2020 11:59'	System	12 Oct 2020 15:31:25

US3212394

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
Data entry locked.	System	12 Oct 2020 15:31:25
User entered 'Day 5'	System	12 Oct 2020 15:31:25

US3212394

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:51:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-10-16T19:41:50', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'f060f117-b4ab-4db0-a713-980b5c6975bd'	System	17 Oct 2020 00:42:09
User entered 'Yes (Y)'	System	17 Oct 2020 00:42:09

US3212394

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:51:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-10-16T19:41:55', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'f060f117-b4ab-4db0-a713-980b5c6975bd'	System	17 Oct 2020 00:42:09
User entered '98.4'	System	17 Oct 2020 00:42:09

US3212394

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:51:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-10-16T19:41:59', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'f060f117-b4ab-4db0-a713-980b5c6975bd'	System	17 Oct 2020 00:42:09
User entered 'No (N)'	System	17 Oct 2020 00:42:09

US3212394

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:51:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-10-16T19:42:02', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'f060f117-b4ab-4db0-a713-980b5c6975bd'	System	17 Oct 2020 00:42:09
User entered '16 Oct 2020 19:42'	System	17 Oct 2020 00:42:09

US3212394

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:51:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
User entered '16 Oct 2020 12:00'	System	12 Oct 2020 15:31:25

US3212394

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:51:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
User entered '17 Oct 2020 11:59'	System	12 Oct 2020 15:31:25

US3212394

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
Data entry locked.	System	12 Oct 2020 15:31:25
User entered 'Day 6'	System	12 Oct 2020 15:31:25

US3212394

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:51:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-10-17T20:32:41', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '6cf26f2f-a086-4c53-96b8-46de25f222d7'	System	18 Oct 2020 01:32:55
User entered 'Yes (Y)'	System	18 Oct 2020 01:32:55

US3212394

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:51:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-10-17T20:32:44', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '6cf26f2f-a086-4c53-96b8-46de25f222d7'	System	18 Oct 2020 01:32:55
User entered '98.7'	System	18 Oct 2020 01:32:55

US3212394

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:51:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-10-17T20:32:47', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '6cf26f2f-a086-4c53-96b8-46de25f222d7'	System	18 Oct 2020 01:32:55
User entered 'No (N)'	System	18 Oct 2020 01:32:55

US3212394

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:51:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-10-17T20:32:50', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '6cf26f2f-a086-4c53-96b8-46de25f222d7'	System	18 Oct 2020 01:32:55
User entered '17 Oct 2020 20:32'	System	18 Oct 2020 01:32:55

US3212394

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:51:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
User entered '17 Oct 2020 12:00'	System	12 Oct 2020 15:31:25

US3212394

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:51:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
User entered '18 Oct 2020 11:59'	System	12 Oct 2020 15:31:25

US3212394

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
Data entry locked.	System	12 Oct 2020 15:31:25
User entered 'Day 7'	System	12 Oct 2020 15:31:25

US3212394

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:51:18

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-10-18T17:19:30', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '59b3e6f3-eb05-4734-a216-5e094d535876'	System	18 Oct 2020 22:20:09
User entered 'Yes (Y)'	System	18 Oct 2020 22:20:09

US3212394

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:51:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-10-18T17:19:39', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '59b3e6f3-eb05-4734-a216-5e094d535876'	System	18 Oct 2020 22:20:09
User entered '98.9'	System	18 Oct 2020 22:20:09

US3212394

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:51:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-10-18T17:20:02', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '59b3e6f3-eb05-4734-a216-5e094d535876'	System	18 Oct 2020 22:20:09
User entered 'No (N)'	System	18 Oct 2020 22:20:09

US3212394

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:51:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-10-18T17:20:05', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '59b3e6f3-eb05-4734-a216-5e094d535876'	System	18 Oct 2020 22:20:09
User entered '18 Oct 2020 17:20'	System	18 Oct 2020 22:20:09

US3212394

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:51:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
User entered '18 Oct 2020 12:00'	System	12 Oct 2020 15:31:25

US3212394

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:51:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
User entered '19 Oct 2020 11:59'	System	12 Oct 2020 15:31:25

US3212394

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
Data entry locked.	System	12 Oct 2020 15:31:25
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	12 Oct 2020 15:31:25

US3212394

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:51:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-10-12T11:01:34', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '2d41c78e-85c8-4ae0-8a22-ee7f6ec5a690'	System	12 Oct 2020 16:02:00
User entered 'None (1)'	System	12 Oct 2020 16:02:00

US3212394

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:51:18

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-10-12T11:01:37', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '2d41c78e-85c8-4ae0-8a22-ee7f6ec5a690'	System	12 Oct 2020 16:02:00
User entered 'No (N)'	System	12 Oct 2020 16:02:00

US3212394

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:51:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-10-12T11:01:40', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '2d41c78e-85c8-4ae0-8a22-ee7f6ec5a690'	System	12 Oct 2020 16:02:00
User entered 'No (N)'	System	12 Oct 2020 16:02:00

US3212394

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:51:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-10-12T11:01:45', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '2d41c78e-85c8-4ae0-8a22-ee7f6ec5a690'	System	12 Oct 2020 16:02:00
User entered 'None (1)'	System	12 Oct 2020 16:02:00

US3212394

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:51:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-10-12T11:01:49', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '2d41c78e-85c8-4ae0-8a22-ee7f6ec5a690'	System	12 Oct 2020 16:02:00
User entered '12 Oct 2020 11:01'	System	12 Oct 2020 16:02:00

US3212394

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:51:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
User entered '12 Oct 2020 10:45'	System	12 Oct 2020 15:31:25

US3212394

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:51:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
User entered '12 Oct 2020 13:15'	System	12 Oct 2020 15:31:25

US3212394

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
Data entry locked.	System	12 Oct 2020 15:31:25
User entered 'Day 1, after vaccination (at home)'	System	12 Oct 2020 15:31:25

US3212394

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:51:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-10-12T20:34:24', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '72b5fc76-8949-4229-91a3-339a28ccc954'	System	13 Oct 2020 01:34:41
User entered 'None (1)'	System	13 Oct 2020 01:34:41

US3212394

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:51:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-10-12T20:34:27', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '72b5fc76-8949-4229-91a3-339a28ccc954'	System	13 Oct 2020 01:34:41
User entered 'No (N)'	System	13 Oct 2020 01:34:41

US3212394

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:51:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-10-12T20:34:31', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '72b5fc76-8949-4229-91a3-339a28ccc954'	System	13 Oct 2020 01:34:41
User entered 'No (N)'	System	13 Oct 2020 01:34:41

US3212394

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:51:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-10-12T20:34:34', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '72b5fc76-8949-4229-91a3-339a28ccc954'	System	13 Oct 2020 01:34:41
User entered 'None (1)'	System	13 Oct 2020 01:34:41

US3212394

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:51:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-10-12T20:34:37', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '72b5fc76-8949-4229-91a3-339a28ccc954'	System	13 Oct 2020 01:34:41
User entered '12 Oct 2020 20:34'	System	13 Oct 2020 01:34:41

US3212394

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:51:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
User entered '12 Oct 2020 14:10'	System	12 Oct 2020 15:31:25

US3212394

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:51:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
User entered '13 Oct 2020 11:59'	System	12 Oct 2020 15:31:25

US3212394

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
Data entry locked.	System	12 Oct 2020 15:31:25
User entered 'Day 2'	System	12 Oct 2020 15:31:25

US3212394

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:51:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-10-13T16:57:32', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'a7e87917-12e9-44cd-a423-ac1651dc595c'	System	13 Oct 2020 21:57:50
User entered 'None (1)'	System	13 Oct 2020 21:57:50

US3212394

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:51:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-10-13T16:57:35', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'a7e87917-12e9-44cd-a423-ac1651dc595c'	System	13 Oct 2020 21:57:50
User entered 'No (N)'	System	13 Oct 2020 21:57:50

US3212394

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:51:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-10-13T16:57:37', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'a7e87917-12e9-44cd-a423-ac1651dc595c'	System	13 Oct 2020 21:57:50
User entered 'No (N)'	System	13 Oct 2020 21:57:50

US3212394

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:51:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-10-13T16:57:39', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'a7e87917-12e9-44cd-a423-ac1651dc595c'	System	13 Oct 2020 21:57:50
User entered 'None (1)'	System	13 Oct 2020 21:57:50

US3212394

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:51:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-10-13T16:57:47', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'a7e87917-12e9-44cd-a423-ac1651dc595c'	System	13 Oct 2020 21:57:50
User entered '13 Oct 2020 16:57'	System	13 Oct 2020 21:57:50

US3212394

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:51:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
User entered '13 Oct 2020 12:00'	System	12 Oct 2020 15:31:25

US3212394

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:51:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
User entered '14 Oct 2020 11:59'	System	12 Oct 2020 15:31:25

US3212394

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
Data entry locked.	System	12 Oct 2020 15:31:25
User entered 'Day 3'	System	12 Oct 2020 15:31:25

US3212394

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:51:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-10-14T17:32:26', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '7115c19e-e95e-456d-8275-7feec6173eb8'	System	14 Oct 2020 22:32:44
User entered 'None (1)'	System	14 Oct 2020 22:32:44

US3212394

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:51:18

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-10-14T17:32:29', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '7115c19e-e95e-456d-8275-7feec6173eb8'	System	14 Oct 2020 22:32:44
User entered 'No (N)'	System	14 Oct 2020 22:32:44

US3212394

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:51:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-10-14T17:32:32', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '7115c19e-e95e-456d-8275-7feec6173eb8'	System	14 Oct 2020 22:32:44
User entered 'No (N)'	System	14 Oct 2020 22:32:44

US3212394

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:51:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-10-14T17:32:35', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '7115c19e-e95e-456d-8275-7feec6173eb8'	System	14 Oct 2020 22:32:44
User entered 'None (1)'	System	14 Oct 2020 22:32:44

US3212394

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:51:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-10-14T17:32:38', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '7115c19e-e95e-456d-8275-7feec6173eb8'	System	14 Oct 2020 22:32:44
User entered '14 Oct 2020 17:32'	System	14 Oct 2020 22:32:44

US3212394

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:51:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
User entered '14 Oct 2020 12:00'	System	12 Oct 2020 15:31:25

US3212394

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:51:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
User entered '15 Oct 2020 11:59'	System	12 Oct 2020 15:31:25

US3212394

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
Data entry locked.	System	12 Oct 2020 15:31:25
User entered 'Day 4'	System	12 Oct 2020 15:31:25

US3212394

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:51:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-10-15T17:48:28', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '0a05fa5b-62ec-4ea8-a0e4-5c3b815df4a1'	System	15 Oct 2020 22:48:41
User entered 'None (1)'	System	15 Oct 2020 22:48:41

US3212394

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:51:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-10-15T17:48:31', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '0a05fa5b-62ec-4ea8-a0e4-5c3b815df4a1'	System	15 Oct 2020 22:48:41
User entered 'No (N)'	System	15 Oct 2020 22:48:41

US3212394

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:51:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-10-15T17:48:33', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '0a05fa5b-62ec-4ea8-a0e4-5c3b815df4a1'	System	15 Oct 2020 22:48:41
User entered 'No (N)'	System	15 Oct 2020 22:48:41

US3212394

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:51:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-10-15T17:48:35', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '0a05fa5b-62ec-4ea8-a0e4-5c3b815df4a1'	System	15 Oct 2020 22:48:41
User entered 'None (1)'	System	15 Oct 2020 22:48:41

US3212394

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:51:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-10-15T17:48:37', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '0a05fa5b-62ec-4ea8-a0e4-5c3b815df4a1'	System	15 Oct 2020 22:48:41
User entered '15 Oct 2020 17:48'	System	15 Oct 2020 22:48:41

US3212394

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:51:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
User entered '15 Oct 2020 12:00'	System	12 Oct 2020 15:31:25

US3212394

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:51:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
User entered '16 Oct 2020 11:59'	System	12 Oct 2020 15:31:25

US3212394

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
Data entry locked.	System	12 Oct 2020 15:31:25
User entered 'Day 5'	System	12 Oct 2020 15:31:25

US3212394

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:51:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-10-16T19:42:07', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '3b523185-df19-4ab8-8d9d-b5e1983a841a'	System	17 Oct 2020 00:42:25
User entered 'Does not interfere with activity (2)'	System	17 Oct 2020 00:42:25

US3212394

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:51:18

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-10-16T19:42:11', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '3b523185-df19-4ab8-8d9d-b5e1983a841a'	System	17 Oct 2020 00:42:25
User entered 'No (N)'	System	17 Oct 2020 00:42:25

US3212394

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:51:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-10-16T19:42:13', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '3b523185-df19-4ab8-8d9d-b5e1983a841a'	System	17 Oct 2020 00:42:25
User entered 'No (N)'	System	17 Oct 2020 00:42:25

US3212394

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:51:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-10-16T19:42:19', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '3b523185-df19-4ab8-8d9d-b5e1983a841a'	System	17 Oct 2020 00:42:25
User entered 'None (1)'	System	17 Oct 2020 00:42:25

US3212394

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:51:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-10-16T19:42:21', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '3b523185-df19-4ab8-8d9d-b5e1983a841a'	System	17 Oct 2020 00:42:25
User entered '16 Oct 2020 19:42'	System	17 Oct 2020 00:42:25

US3212394

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:51:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
User entered '16 Oct 2020 12:00'	System	12 Oct 2020 15:31:25

US3212394

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:51:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
User entered '17 Oct 2020 11:59'	System	12 Oct 2020 15:31:25

US3212394

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
Data entry locked.	System	12 Oct 2020 15:31:25
User entered 'Day 6'	System	12 Oct 2020 15:31:25

US3212394

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:51:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-10-17T20:32:53', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '1a6d32b3-8b58-4997-b975-2477b06b7ef5'	System	18 Oct 2020 01:33:07
User entered 'None (1)'	System	18 Oct 2020 01:33:07

US3212394

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:51:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-10-17T20:32:56', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '1a6d32b3-8b58-4997-b975-2477b06b7ef5'	System	18 Oct 2020 01:33:07
User entered 'No (N)'	System	18 Oct 2020 01:33:07

US3212394

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:51:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-10-17T20:32:58', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '1a6d32b3-8b58-4997-b975-2477b06b7ef5'	System	18 Oct 2020 01:33:07
User entered 'No (N)'	System	18 Oct 2020 01:33:07

US3212394

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:51:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-10-17T20:33:00', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '1a6d32b3-8b58-4997-b975-2477b06b7ef5'	System	18 Oct 2020 01:33:07
User entered 'None (1)'	System	18 Oct 2020 01:33:07

US3212394

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:51:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-10-17T20:33:02', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '1a6d32b3-8b58-4997-b975-2477b06b7ef5'	System	18 Oct 2020 01:33:07
User entered '17 Oct 2020 20:33'	System	18 Oct 2020 01:33:07

US3212394

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:51:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
User entered '17 Oct 2020 12:00'	System	12 Oct 2020 15:31:25

US3212394

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:51:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
User entered '18 Oct 2020 11:59'	System	12 Oct 2020 15:31:25

US3212394

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
Data entry locked.	System	12 Oct 2020 15:31:25
User entered 'Day 7'	System	12 Oct 2020 15:31:25

US3212394

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:51:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-10-18T17:20:15', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '405bb667-81c1-45b9-991b-062ed8b6c3f7'	System	18 Oct 2020 22:20:32
User entered 'None (1)'	System	18 Oct 2020 22:20:32

US3212394

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:51:18

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-10-18T17:20:22', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '405bb667-81c1-45b9-991b-062ed8b6c3f7'	System	18 Oct 2020 22:20:32
User entered 'No (N)'	System	18 Oct 2020 22:20:32

US3212394

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:51:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-10-18T17:20:23', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '405bb667-81c1-45b9-991b-062ed8b6c3f7'	System	18 Oct 2020 22:20:32
User entered 'No (N)'	System	18 Oct 2020 22:20:32

US3212394

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:51:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-10-18T17:20:25', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '405bb667-81c1-45b9-991b-062ed8b6c3f7'	System	18 Oct 2020 22:20:32
User entered 'None (1)'	System	18 Oct 2020 22:20:32

US3212394

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:51:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-10-18T17:20:27', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '405bb667-81c1-45b9-991b-062ed8b6c3f7'	System	18 Oct 2020 22:20:32
User entered '18 Oct 2020 17:20'	System	18 Oct 2020 22:20:32

US3212394

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:51:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
User entered '18 Oct 2020 12:00'	System	12 Oct 2020 15:31:25

US3212394

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:51:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
User entered '19 Oct 2020 11:59'	System	12 Oct 2020 15:31:25

US3212394

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
Data entry locked.	System	12 Oct 2020 15:31:25
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	12 Oct 2020 15:31:25

US3212394

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:51:18

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-10-12T11:01:53', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'f511b29d-6442-4f13-aa5b-fd5a37a686a5'	System	12 Oct 2020 16:02:17
User entered 'None (0)'	System	12 Oct 2020 16:02:17

US3212394

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:51:18

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-10-12T11:01:55', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'f511b29d-6442-4f13-aa5b-fd5a37a686a5'	System	12 Oct 2020 16:02:17
User entered 'None (0)'	System	12 Oct 2020 16:02:17

US3212394

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:51:18

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-10-12T11:01:57', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'f511b29d-6442-4f13-aa5b-fd5a37a686a5'	System	12 Oct 2020 16:02:17
User entered 'None (0)'	System	12 Oct 2020 16:02:17

US3212394

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:51:18

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-10-12T11:02:00', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'f511b29d-6442-4f13-aa5b-fd5a37a686a5'	System	12 Oct 2020 16:02:17
User entered 'None (0)'	System	12 Oct 2020 16:02:17

US3212394

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:51:18

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-10-12T11:02:02', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'f511b29d-6442-4f13-aa5b-fd5a37a686a5'	System	12 Oct 2020 16:02:17
User entered 'None (0)'	System	12 Oct 2020 16:02:17

US3212394

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:51:18

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-10-12T11:02:04', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'f511b29d-6442-4f13-aa5b-fd5a37a686a5'	System	12 Oct 2020 16:02:17
User entered 'None (0)'	System	12 Oct 2020 16:02:17

US3212394

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:51:18

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)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-10-12T11:02:09', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'f511b29d-6442-4f13-aa5b-fd5a37a686a5'	System	12 Oct 2020 16:02:17
User entered 'No (N)'	System	12 Oct 2020 16:02:17

US3212394

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:51:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-10-12T11:02:11', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'f511b29d-6442-4f13-aa5b-fd5a37a686a5'	System	12 Oct 2020 16:02:17
User entered '12 Oct 2020 11:02'	System	12 Oct 2020 16:02:17

US3212394

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:51:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
User entered '12 Oct 2020 10:45'	System	12 Oct 2020 15:31:25

US3212394

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:51:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
User entered '12 Oct 2020 13:15'	System	12 Oct 2020 15:31:25

US3212394

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
Data entry locked.	System	12 Oct 2020 15:31:25
User entered 'Day 1, after vaccination (at home)'	System	12 Oct 2020 15:31:25

US3212394

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:51:18

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-10-12T20:34:42', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'b037b64f-fb3b-403c-bad8-ce56e2befc13'	System	13 Oct 2020 01:35:10
User entered 'None (0)'	System	13 Oct 2020 01:35:10

US3212394

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:51:18

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-10-12T20:34:44', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'b037b64f-fb3b-403c-bad8-ce56e2befc13'	System	13 Oct 2020 01:35:10
User entered 'None (0)'	System	13 Oct 2020 01:35:10

US3212394

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:51:18

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-10-12T20:34:47', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'b037b64f-fb3b-403c-bad8-ce56e2befc13'	System	13 Oct 2020 01:35:10
User entered 'None (0)'	System	13 Oct 2020 01:35:10

US3212394

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:51:18

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-10-12T20:34:50', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'b037b64f-fb3b-403c-bad8-ce56e2befc13'	System	13 Oct 2020 01:35:10
User entered 'None (0)'	System	13 Oct 2020 01:35:10

US3212394

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:51:18

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-10-12T20:34:52', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'b037b64f-fb3b-403c-bad8-ce56e2befc13'	System	13 Oct 2020 01:35:10
User entered 'None (0)'	System	13 Oct 2020 01:35:10

US3212394

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:51:18

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-10-12T20:34:54', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'b037b64f-fb3b-403c-bad8-ce56e2befc13'	System	13 Oct 2020 01:35:10
User entered 'None (0)'	System	13 Oct 2020 01:35:10

US3212394

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:51:18

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)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-10-12T20:35:01', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'b037b64f-fb3b-403c-bad8-ce56e2befc13'	System	13 Oct 2020 01:35:10
User entered 'No (N)'	System	13 Oct 2020 01:35:10

US3212394

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:51:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-10-12T20:35:05', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'b037b64f-fb3b-403c-bad8-ce56e2befc13'	System	13 Oct 2020 01:35:10
User entered '12 Oct 2020 20:35'	System	13 Oct 2020 01:35:10

US3212394

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:51:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
User entered '12 Oct 2020 14:10'	System	12 Oct 2020 15:31:25

US3212394

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:51:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
User entered '13 Oct 2020 11:59'	System	12 Oct 2020 15:31:25

US3212394

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
Data entry locked.	System	12 Oct 2020 15:31:25
User entered 'Day 2'	System	12 Oct 2020 15:31:25

US3212394

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:51:18

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-10-13T16:57:50', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '9c353177-45bb-44a9-992b-d6cede408a66'	System	13 Oct 2020 21:58:08
User entered 'None (0)'	System	13 Oct 2020 21:58:08

US3212394

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:51:18

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-10-13T16:57:52', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '9c353177-45bb-44a9-992b-d6cede408a66'	System	13 Oct 2020 21:58:08
User entered 'None (0)'	System	13 Oct 2020 21:58:08

US3212394

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:51:18

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-10-13T16:57:53', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '9c353177-45bb-44a9-992b-d6cede408a66'	System	13 Oct 2020 21:58:08
User entered 'None (0)'	System	13 Oct 2020 21:58:08

US3212394

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:51:18

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-10-13T16:57:55', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '9c353177-45bb-44a9-992b-d6cede408a66'	System	13 Oct 2020 21:58:08
User entered 'None (0)'	System	13 Oct 2020 21:58:08

US3212394

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:51:18

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-10-13T16:57:56', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '9c353177-45bb-44a9-992b-d6cede408a66'	System	13 Oct 2020 21:58:08
User entered 'None (0)'	System	13 Oct 2020 21:58:08

US3212394

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:51:18

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-10-13T16:57:58', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '9c353177-45bb-44a9-992b-d6cede408a66'	System	13 Oct 2020 21:58:08
User entered 'None (0)'	System	13 Oct 2020 21:58:08

US3212394

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:51:18

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)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-10-13T16:58:01', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '9c353177-45bb-44a9-992b-d6cede408a66'	System	13 Oct 2020 21:58:08
User entered 'No (N)'	System	13 Oct 2020 21:58:08

US3212394

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:51:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-10-13T16:58:04', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '9c353177-45bb-44a9-992b-d6cede408a66'	System	13 Oct 2020 21:58:08
User entered '13 Oct 2020 16:58'	System	13 Oct 2020 21:58:08

US3212394

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:51:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
User entered '13 Oct 2020 12:00'	System	12 Oct 2020 15:31:25

US3212394

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:51:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
User entered '14 Oct 2020 11:59'	System	12 Oct 2020 15:31:25

US3212394

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
Data entry locked.	System	12 Oct 2020 15:31:25
User entered 'Day 3'	System	12 Oct 2020 15:31:25

US3212394

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:51:18

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-10-14T17:43:42', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '383c252e-a471-4fbf-bd73-cbe9d6b0d89f'	System	14 Oct 2020 22:44:08
User entered 'None (0)'	System	14 Oct 2020 22:44:08

US3212394

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:51:18

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-10-14T17:43:45', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '383c252e-a471-4fbf-bd73-cbe9d6b0d89f'	System	14 Oct 2020 22:44:08
User entered 'None (0)'	System	14 Oct 2020 22:44:08

US3212394

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:51:18

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-10-14T17:43:47', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '383c252e-a471-4fbf-bd73-cbe9d6b0d89f'	System	14 Oct 2020 22:44:08
User entered 'None (0)'	System	14 Oct 2020 22:44:08

US3212394

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:51:18

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-10-14T17:43:49', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '383c252e-a471-4fbf-bd73-cbe9d6b0d89f' User entered 'None (0)'	System	14 Oct 2020 22:44:08
	System	14 Oct 2020 22:44:08

US3212394

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:51:18

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-10-14T17:43:51', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '383c252e-a471-4fbf-bd73-cbe9d6b0d89f'	System	14 Oct 2020 22:44:08
User entered 'None (0)'	System	14 Oct 2020 22:44:08

US3212394

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:51:18

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-10-14T17:43:53', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '383c252e-a471-4fbf-bd73-cbe9d6b0d89f'	System	14 Oct 2020 22:44:08
User entered 'None (0)'	System	14 Oct 2020 22:44:08

US3212394

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:51:18

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)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-10-14T17:43:57', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '383c252e-a471-4fbf-bd73-cbe9d6b0d89f'	System	14 Oct 2020 22:44:08
User entered 'No (N)'	System	14 Oct 2020 22:44:08

US3212394

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:51:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-10-14T17:43:59', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '383c252e-a471-4fbf-bd73-cbe9d6b0d89f'	System	14 Oct 2020 22:44:08
User entered '14 Oct 2020 17:43'	System	14 Oct 2020 22:44:08

US3212394

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:51:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
User entered '14 Oct 2020 12:00'	System	12 Oct 2020 15:31:25

US3212394

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:51:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
User entered '15 Oct 2020 11:59'	System	12 Oct 2020 15:31:25

US3212394

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
Data entry locked.	System	12 Oct 2020 15:31:25
User entered 'Day 4'	System	12 Oct 2020 15:31:25

US3212394

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:51:18

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-10-15T17:48:41', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '7aebe142-f49a-4522-a540-dc00ca0c8717'	System	15 Oct 2020 22:48:59
User entered 'None (0)'	System	15 Oct 2020 22:48:59

US3212394

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:51:18

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-10-15T17:48:43', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '7aebe142-f49a-4522-a540-dc00ca0c8717'	System	15 Oct 2020 22:48:59
User entered 'None (0)'	System	15 Oct 2020 22:48:59

US3212394

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:51:18

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-10-15T17:48:45', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '7aebe142-f49a-4522-a540-dc00ca0c8717'	System	15 Oct 2020 22:48:59
User entered 'None (0)'	System	15 Oct 2020 22:48:59

US3212394

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:51:18

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-10-15T17:48:47', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '7aebe142-f49a-4522-a540-dc00ca0c8717'	System	15 Oct 2020 22:48:59
User entered 'None (0)'	System	15 Oct 2020 22:48:59

US3212394

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:51:18

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-10-15T17:48:48', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '7aebe142-f49a-4522-a540-dc00ca0c8717'	System	15 Oct 2020 22:48:59
User entered 'None (0)'	System	15 Oct 2020 22:48:59

US3212394

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:51:18

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-10-15T17:48:50', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '7aebe142-f49a-4522-a540-dc00ca0c8717'	System	15 Oct 2020 22:48:59
User entered 'None (0)'	System	15 Oct 2020 22:48:59

US3212394

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:51:18

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)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-10-15T17:48:52', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '7aebe142-f49a-4522-a540-dc00ca0c8717'	System	15 Oct 2020 22:48:59
User entered 'No (N)'	System	15 Oct 2020 22:48:59

US3212394

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:51:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-10-15T17:48:55', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '7aebe142-f49a-4522-a540-dc00ca0c8717'	System	15 Oct 2020 22:48:59
User entered '15 Oct 2020 17:48'	System	15 Oct 2020 22:48:59

US3212394

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:51:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
User entered '15 Oct 2020 12:00'	System	12 Oct 2020 15:31:25

US3212394

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:51:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
User entered '16 Oct 2020 11:59'	System	12 Oct 2020 15:31:25

US3212394

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
Data entry locked.	System	12 Oct 2020 15:31:25
User entered 'Day 5'	System	12 Oct 2020 15:31:25

US3212394

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:51:18

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-10-16T19:42:25', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'a49a9b41-891c-4153-bfde-4411ffbfa2dc'	System	17 Oct 2020 00:42:42
User entered 'None (0)'	System	17 Oct 2020 00:42:42

US3212394

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:51:18

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-10-16T19:42:26', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'a49a9b41-891c-4153-bfde-4411ffbfa2dc'	System	17 Oct 2020 00:42:42
User entered 'None (0)'	System	17 Oct 2020 00:42:42

US3212394

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:51:18

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-10-16T19:42:28', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'a49a9b41-891c-4153-bfde-4411ffbfa2dc'	System	17 Oct 2020 00:42:42
User entered 'None (0)'	System	17 Oct 2020 00:42:42

US3212394

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:51:18

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-10-16T19:42:30', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'a49a9b41-891c-4153-bfde-4411ffbfa2dc'	System	17 Oct 2020 00:42:42
User entered 'None (0)'	System	17 Oct 2020 00:42:42

US3212394

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:51:18

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-10-16T19:42:32', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'a49a9b41-891c-4153-bfde-4411ffbfa2dc'	System	17 Oct 2020 00:42:42
User entered 'None (0)'	System	17 Oct 2020 00:42:42

US3212394

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:51:18

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-10-16T19:42:34', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'a49a9b41-891c-4153-bfde-4411ffbfa2dc'	System	17 Oct 2020 00:42:42
User entered 'None (0)'	System	17 Oct 2020 00:42:42

US3212394

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:51:18

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)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-10-16T19:42:36', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'a49a9b41-891c-4153-bfde-4411ffbfa2dc'	System	17 Oct 2020 00:42:42
User entered 'No (N)'	System	17 Oct 2020 00:42:42

US3212394

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:51:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-10-16T19:42:38', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'a49a9b41-891c-4153-bfde-4411ffbfa2dc'	System	17 Oct 2020 00:42:42
User entered '16 Oct 2020 19:42'	System	17 Oct 2020 00:42:42

US3212394

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:51:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
User entered '16 Oct 2020 12:00'	System	12 Oct 2020 15:31:25

US3212394

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:51:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
User entered '17 Oct 2020 11:59'	System	12 Oct 2020 15:31:25

US3212394

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
Data entry locked.	System	12 Oct 2020 15:31:25
User entered 'Day 6'	System	12 Oct 2020 15:31:25

US3212394

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:51:18

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-10-17T20:33:05', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'fccfad20-85c0-42af-8d33-53219c4a6d12'	System	18 Oct 2020 01:33:21
User entered 'None (0)'	System	18 Oct 2020 01:33:21

US3212394

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:51:18

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-10-17T20:33:07', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'fccfad20-85c0-42af-8d33-53219c4a6d12'	System	18 Oct 2020 01:33:21
User entered 'None (0)'	System	18 Oct 2020 01:33:21

US3212394

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:51:18

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-10-17T20:33:09', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'fccfad20-85c0-42af-8d33-53219c4a6d12'	System	18 Oct 2020 01:33:21
User entered 'None (0)'	System	18 Oct 2020 01:33:21

US3212394

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:51:18

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-10-17T20:33:10', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'fccfad20-85c0-42af-8d33-53219c4a6d12'	System	18 Oct 2020 01:33:21
User entered 'None (0)'	System	18 Oct 2020 01:33:21

US3212394

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:51:18

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-10-17T20:33:12', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'fccfad20-85c0-42af-8d33-53219c4a6d12'	System	18 Oct 2020 01:33:21
User entered 'None (0)'	System	18 Oct 2020 01:33:21

US3212394

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:51:18

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-10-17T20:33:13', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'fccfad20-85c0-42af-8d33-53219c4a6d12'	System	18 Oct 2020 01:33:21
User entered 'None (0)'	System	18 Oct 2020 01:33:21

US3212394

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:51:18

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)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-10-17T20:33:15', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'fccfad20-85c0-42af-8d33-53219c4a6d12'	System	18 Oct 2020 01:33:21
User entered 'No (N)'	System	18 Oct 2020 01:33:21

US3212394

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:51:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-10-17T20:33:17', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'fccfad20-85c0-42af-8d33-53219c4a6d12'	System	18 Oct 2020 01:33:21
User entered '17 Oct 2020 20:33'	System	18 Oct 2020 01:33:21

US3212394

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:51:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
User entered '17 Oct 2020 12:00'	System	12 Oct 2020 15:31:25

US3212394

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:51:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
User entered '18 Oct 2020 11:59'	System	12 Oct 2020 15:31:25

US3212394

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
Data entry locked.	System	12 Oct 2020 15:31:25
User entered 'Day 7'	System	12 Oct 2020 15:31:25

US3212394

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:51:18

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-10-18T17:20:31', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'e07bde24-ca4f-4605-8b6d-3faeedb39455'	System	18 Oct 2020 22:21:00
User entered 'None (0)'	System	18 Oct 2020 22:21:00

US3212394

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:51:18

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-10-18T17:20:33', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'e07bde24-ca4f-4605-8b6d-3faeedb39455'	System	18 Oct 2020 22:21:00
User entered 'None (0)'	System	18 Oct 2020 22:21:00

US3212394

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:51:18

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-10-18T17:20:34', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'e07bde24-ca4f-4605-8b6d-3faeedb39455'	System	18 Oct 2020 22:21:00
User entered 'None (0)'	System	18 Oct 2020 22:21:00

US3212394

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:51:18

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-10-18T17:20:36', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'e07bde24-ca4f-4605-8b6d-3faeedb39455'	System	18 Oct 2020 22:21:00
User entered 'None (0)'	System	18 Oct 2020 22:21:00

US3212394

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:51:18

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-10-18T17:20:37', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'e07bde24-ca4f-4605-8b6d-3faeedb39455'	System	18 Oct 2020 22:21:00
User entered 'None (0)'	System	18 Oct 2020 22:21:00

US3212394

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:51:18

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-10-18T17:20:39', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'e07bde24-ca4f-4605-8b6d-3faeedb39455'	System	18 Oct 2020 22:21:00
User entered 'None (0)'	System	18 Oct 2020 22:21:00

US3212394

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:51:18

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)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-10-18T17:20:47', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'e07bde24-ca4f-4605-8b6d-3faedb39455'	System	18 Oct 2020 22:21:00
User entered 'No (N)'	System	18 Oct 2020 22:21:00

US3212394

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:51:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-10-18T17:20:55', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'e07bde24-ca4f-4605-8b6d-3faeedb39455'	System	18 Oct 2020 22:21:00
User entered '18 Oct 2020 17:20'	System	18 Oct 2020 22:21:00

US3212394

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:51:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
User entered '18 Oct 2020 12:00'	System	12 Oct 2020 15:31:25

US3212394

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:51:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
User entered '19 Oct 2020 11:59'	System	12 Oct 2020 15:31:25

US3212394

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:51:18

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:27
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 22:01:13
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	20 Oct 2020 14:57:45

US3212394

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:51:18

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:27
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 22:01:13
User entered '19 Oct 2020'	Laura Ngansop Djampou (b) (4)	20 Oct 2020 14:57:45

US3212394

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:51:18

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:27
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 22:01:13
User entered 'Contact Made (CONTACT MADE)'	Laura Ngansop Djampou (b) (4)	20 Oct 2020 14:57:45

US3212394

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:51:18

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:27
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 22:01:13
User entered empty.	Laura Ngansop Djampou (b) (4)	20 Oct 2020 14:57:45

US3212394

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:51:18

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:27
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 22:01:17
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	20 Oct 2020 14:57:51

US3212394

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:51:18

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:27
User entered 'I'	System	20 Oct 2020 14:57:51

US3212394

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:51:18

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:27
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 22:01:56
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	27 Oct 2020 15:01:44

US3212394

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:51:18

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:27
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 22:01:56
User entered '26 Oct 2020'	Laura Ngansop Djampou (b) (4)	27 Oct 2020 15:01:44

US3212394

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:51:18

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:27
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 22:01:56
User entered 'Contact Made (CONTACT MADE)'	Laura Ngansop Djampou (b) (4)	27 Oct 2020 15:01:44

US3212394

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:51:18

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:27
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 22:01:56
User entered empty.	Laura Ngansop Djampou (b) (4)	27 Oct 2020 15:01:44

US3212394

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:51:18

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:27
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 22:02:01
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	27 Oct 2020 15:01:59

US3212394

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:51:18

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:27
User entered 'I'	System	27 Oct 2020 15:01:59

US3212394

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:51:18

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:27
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	07 Dec 2020 22:37:22
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	06 Nov 2020 16:28:01

US3212394

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:51:18

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:27
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	07 Dec 2020 22:37:22
User entered '02 Nov 2020' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	07 Dec 2020 20:15:29
User entered '2 Nov 2020'	Laura Ngansop Djampou (b) (4)	06 Nov 2020 16:28:01

US3212394

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:51:18

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:27
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	07 Dec 2020 22:37:22
User entered 'Contact Made (CONTACT MADE)'	Laura Ngansop Djampou (b) (4)	06 Nov 2020 16:28:01

US3212394

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:51:18

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:27
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	07 Dec 2020 22:37:22
User entered empty.	Laura Ngansop Djampou (b) (4)	06 Nov 2020 16:28:01

US3212394

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:51:18

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:27
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	07 Dec 2020 22:37:33
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	06 Nov 2020 16:28:18

US3212394

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:51:18

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:27
User entered 'I'	System	06 Nov 2020 16:28:18

US3212394

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:51:18

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	07 Dec 2020 22:37:55
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	13 Nov 2020 21:43:22

US3212394

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:51:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	07 Dec 2020 22:37:55
User entered '13 Nov 2020'	Laura Ngansop Djampou (b) (4)	13 Nov 2020 21:43:22

US3212394

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:51:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	07 Dec 2020 22:37:55
User entered 'Clinic (Clinic)'	Laura Ngansop Djampou (b) (4)	13 Nov 2020 21:43:22

US3212394

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:51:18

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:29
User entered 'VISIT3'	System	13 Nov 2020 21:43:22

US3212394

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:51:18

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	07 Dec 2020 22:38:16
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	13 Nov 2020 21:43:54

US3212394

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:51:18

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	07 Dec 2020 22:38:16
User entered '13 Nov 2020'	Laura Ngansop Djampou (b) (4)	13 Nov 2020 21:43:54

US3212394

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:51:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	07 Dec 2020 22:38:16
User entered '14:37' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	16 Nov 2020 14:22:49
User entered '09:10'	Laura Ngansop Djampou (b) (4)	13 Nov 2020 21:43:54

US3212394

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:51:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:29
User entered '13 Nov 2020 14:37'	System	16 Nov 2020 14:22:49
User entered '13 Nov 2020 09:10'	System	13 Nov 2020 21:43:54

US3212394

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:51:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	07 Dec 2020 22:38:16
User entered '97.5' F	Laura Ngansop Djampou (b) (4)	13 Nov 2020 21:43:54

US3212394

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:51:18

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	07 Dec 2020 22:38:16
User entered 'Oral (Oral)'	Laura Ngansop Djampou (b) (4)	13 Nov 2020 21:43:54

US3212394

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:51:18

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	07 Dec 2020 22:38:16
User entered empty.	Laura Ngansop Djampou (b) (4)	13 Nov 2020 21:43:54

US3212394

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:51:18

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	07 Dec 2020 22:38:16
User entered '94' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	16 Nov 2020 14:22:49
User entered '95'	Laura Ngansop Djampou (b) (4)	13 Nov 2020 21:43:54

US3212394

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:51:18

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:29
User entered 'bpm'	System	13 Nov 2020 21:43:54

US3212394

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:51:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	07 Dec 2020 22:38:16
User entered '15' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	16 Nov 2020 14:22:49
User entered '16'	Laura Ngansop Djampou (b) (4)	13 Nov 2020 21:43:54

US3212394

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:51:18

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:29
User entered 'breaths/min'	System	13 Nov 2020 21:43:54

US3212394

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:51:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	07 Dec 2020 22:38:16
User entered '113' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	16 Nov 2020 14:22:49
User entered '108'	Laura Ngansop Djampou (b) (4)	13 Nov 2020 21:43:54

US3212394

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:51:18

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:29
User entered 'mmHg'	System	13 Nov 2020 21:43:54

US3212394

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:51:18

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	07 Dec 2020 22:38:16
User entered '84' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	16 Nov 2020 14:22:49
User entered '79'	Laura Ngansop Djampou (b) (4)	13 Nov 2020 21:43:54

US3212394

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:51:18

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:29
User entered 'mmHg'	System	13 Nov 2020 21:43:54

US3212394

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:51:18

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:29

US3212394

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:51:18

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:29

US3212394

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:51:18

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	07 Dec 2020 22:38:26
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	13 Nov 2020 21:44:06

US3212394

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:51:18

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	07 Dec 2020 22:38:26
User entered '13 Nov 2020'	Laura Ngansop Djampou (b) (4)	13 Nov 2020 21:44:06

US3212394

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:51:18

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	07 Dec 2020 22:38:43
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	13 Nov 2020 21:44:18

US3212394

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:51:18

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	07 Dec 2020 22:38:43
User entered '13 Nov 2020'	Laura Ngansop Djampou (b) (4)	13 Nov 2020 21:44:18

US3212394

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:51:18

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	07 Dec 2020 22:38:43
User entered '15:36' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	16 Nov 2020 14:23:13
User entered '10:11'	Laura Ngansop Djampou (b) (4)	13 Nov 2020 21:44:18

US3212394

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:51:18

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:29
User entered '13 Nov 2020 15:36'	System	16 Nov 2020 14:23:13
User entered '13 Nov 2020 10:11'	System	13 Nov 2020 21:44:18

US3212394

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:51:18

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	07 Dec 2020 22:38:50
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	13 Nov 2020 21:44:24

US3212394

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:51:18

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:29
User entered 'I'	System	13 Nov 2020 21:44:24

US3212394

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
Data entry locked.	System	11 Sep 2020 22:03:51
User entered 'Day 64'	System	11 Sep 2020 22:03:51

US3212394

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[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)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-11-11T17:17:37', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '3a6567fe-ac8d-4a9d-b957-01ad113373ed'	System	11 Nov 2020 23:19:14
User entered 'Yes (Y)'	System	11 Nov 2020 23:19:14

US3212394

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

Have you been exposed to someone with 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)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-11-11T17:17:47', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '3a6567fe-ac8d-4a9d-b957-01ad113373ed'	System	11 Nov 2020 23:19:14
User entered 'No (N)'	System	11 Nov 2020 23:19:14

US3212394

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-11-11T17:18:16', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '3a6567fe-ac8d-4a9d-b957-01ad113373ed'	System	11 Nov 2020 23:19:14
User entered 'No (N)'	System	11 Nov 2020 23:19:14

US3212394

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-11-11T17:18:34', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '3a6567fe-ac8d-4a9d-b957-01ad113373ed'	System	11 Nov 2020 23:19:14
User entered 'Yes (Y)'	System	11 Nov 2020 23:19:14

US3212394

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-11-11T17:18:46', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '3a6567fe-ac8d-4a9d-b957-01ad113373ed'	System	11 Nov 2020 23:19:14
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	11 Nov 2020 23:19:14

US3212394

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-11-11T17:19:04', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '3a6567fe-ac8d-4a9d-b957-01ad113373ed'	System	11 Nov 2020 23:19:14
User entered '11 Nov 2020 17:19:04'	System	11 Nov 2020 23:19:14

US3212394

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
Data entry locked.	System	11 Sep 2020 22:03:51
User entered '11 Nov 2020 00:01'	System	11 Sep 2020 22:03:51

US3212394

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
Data entry locked.	System	11 Sep 2020 22:03:51
User entered '15 Nov 2020 23:59'	System	11 Sep 2020 22:03:51

US3212394

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
Data entry locked.	System	11 Sep 2020 22:03:51
User entered 'Day 71'	System	11 Sep 2020 22:03:51

US3212394

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[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)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-11-18T00:03:15', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'e5330fe7-6f02-4d5a-ab38-bd2f3c41c449'	System	18 Nov 2020 06:04:25
User entered 'Yes (Y)'	System	18 Nov 2020 06:04:25

US3212394

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

Have you been exposed to someone with 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)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-11-18T00:03:20', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'e5330fe7-6f02-4d5a-ab38-bd2f3c41c449'	System	18 Nov 2020 06:04:25
User entered 'No (N)'	System	18 Nov 2020 06:04:25

US3212394

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-11-18T00:03:28', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'e5330fe7-6f02-4d5a-ab38-bd2f3c41c449'	System	18 Nov 2020 06:04:25
User entered 'Yes (Y)'	System	18 Nov 2020 06:04:25

US3212394

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-11-18T00:03:55', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'e5330fe7-6f02-4d5a-ab38-bd2f3c41c449'	System	18 Nov 2020 06:04:25
User entered '0'	System	18 Nov 2020 06:04:25

US3212394

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-11-18T00:03:55', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'e5330fe7-6f02-4d5a-ab38-bd2f3c41c449'	System	18 Nov 2020 06:04:25
User entered '0'	System	18 Nov 2020 06:04:25

US3212394

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-11-18T00:03:55', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'e5330fe7-6f02-4d5a-ab38-bd2f3c41c449'	System	18 Nov 2020 06:04:25
User entered '0'	System	18 Nov 2020 06:04:25

US3212394

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-11-18T00:03:55', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'e5330fe7-6f02-4d5a-ab38-bd2f3c41c449'	System	18 Nov 2020 06:04:25
User entered '0'	System	18 Nov 2020 06:04:25

US3212394

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-11-18T00:03:55', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'e5330fe7-6f02-4d5a-ab38-bd2f3c41c449'	System	18 Nov 2020 06:04:25
User entered '0'	System	18 Nov 2020 06:04:25

US3212394

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-11-18T00:03:55', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'e5330fe7-6f02-4d5a-ab38-bd2f3c41c449'	System	18 Nov 2020 06:04:25
User entered '1'	System	18 Nov 2020 06:04:25

US3212394

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-11-18T00:03:55', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'e5330fe7-6f02-4d5a-ab38-bd2f3c41c449'	System	18 Nov 2020 06:04:25
User entered '0'	System	18 Nov 2020 06:04:25

US3212394

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-11-18T00:03:55', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'e5330fe7-6f02-4d5a-ab38-bd2f3c41c449'	System	18 Nov 2020 06:04:25
User entered '0'	System	18 Nov 2020 06:04:25

US3212394

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-11-18T00:03:55', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'e5330fe7-6f02-4d5a-ab38-bd2f3c41c449'	System	18 Nov 2020 06:04:25
User entered '1'	System	18 Nov 2020 06:04:25

US3212394

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-11-18T00:03:55', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'e5330fe7-6f02-4d5a-ab38-bd2f3c41c449'	System	18 Nov 2020 06:04:25
User entered '0'	System	18 Nov 2020 06:04:25

US3212394

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-11-18T00:03:55', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'e5330fe7-6f02-4d5a-ab38-bd2f3c41c449'	System	18 Nov 2020 06:04:25
User entered '0'	System	18 Nov 2020 06:04:25

US3212394

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-11-18T00:03:55', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'e5330fe7-6f02-4d5a-ab38-bd2f3c41c449'	System	18 Nov 2020 06:04:25
User entered '0'	System	18 Nov 2020 06:04:25

US3212394

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-11-18T00:03:55', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'e5330fe7-6f02-4d5a-ab38-bd2f3c41c449'	System	18 Nov 2020 06:04:25
User entered '0'	System	18 Nov 2020 06:04:25

US3212394

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-11-18T00:03:55', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'e5330fe7-6f02-4d5a-ab38-bd2f3c41c449'	System	18 Nov 2020 06:04:25
User entered '0'	System	18 Nov 2020 06:04:25

US3212394

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-11-18T00:03:55', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'e5330fe7-6f02-4d5a-ab38-bd2f3c41c449'	System	18 Nov 2020 06:04:25
User entered '0'	System	18 Nov 2020 06:04:25

US3212394

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-11-18T00:03:55', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'e5330fe7-6f02-4d5a-ab38-bd2f3c41c449'	System	18 Nov 2020 06:04:25
User entered '0'	System	18 Nov 2020 06:04:25

US3212394

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-11-18T00:03:55', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'e5330fe7-6f02-4d5a-ab38-bd2f3c41c449'	System	18 Nov 2020 06:04:25
User entered '0'	System	18 Nov 2020 06:04:25

US3212394

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-11-18T00:03:59', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'e5330fe7-6f02-4d5a-ab38-bd2f3c41c449'	System	18 Nov 2020 06:04:25
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	18 Nov 2020 06:04:25

US3212394

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-11-18T00:04:06', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'e5330fe7-6f02-4d5a-ab38-bd2f3c41c449'	System	18 Nov 2020 06:04:25
User entered 'No (N)'	System	18 Nov 2020 06:04:25

US3212394

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-11-18T00:04:12', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'e5330fe7-6f02-4d5a-ab38-bd2f3c41c449'	System	18 Nov 2020 06:04:25
User entered '18 Nov 2020 00:04:12'	System	18 Nov 2020 06:04:25

US3212394

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
Data entry locked.	System	11 Sep 2020 22:03:51
User entered '18 Nov 2020 00:01'	System	11 Sep 2020 22:03:51

US3212394

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:27:40
Data entry locked.	System	11 Sep 2020 22:03:51
User entered '22 Nov 2020 23:59'	System	11 Sep 2020 22:03:51

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[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 (b00d7c6802baa9d2)', Time: '2020-11-23T17:07:11', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'e7b650ed-4502-493e-acc2-ee96df1059e9'	System	23 Nov 2020 23:09:57
User entered 'Yes (Y)'	System	23 Nov 2020 23:09:57

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

Have you been exposed to someone with 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 (b00d7c6802baa9d2)', Time: '2020-11-23T17:08:45', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'e7b650ed-4502-493e-acc2-ee96df1059e9'	System	23 Nov 2020 23:09:57
User entered 'No (N)'	System	23 Nov 2020 23:09:57

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[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 (b00d7c6802baa9d2)', Time: '2020-11-23T17:08:49', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'e7b650ed-4502-493e-acc2-ee96df1059e9'	System	23 Nov 2020 23:09:57
User entered 'Yes (Y)'	System	23 Nov 2020 23:09:57

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-11-23T17:09:19', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'e7b650ed-4502-493e-acc2-ee96df1059e9'	System	23 Nov 2020 23:09:57
User entered '0'	System	23 Nov 2020 23:09:57

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-11-23T17:09:19', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'e7b650ed-4502-493e-acc2-ee96df1059e9'	System	23 Nov 2020 23:09:57
User entered '0'	System	23 Nov 2020 23:09:57

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-11-23T17:09:19', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'e7b650ed-4502-493e-acc2-ee96df1059e9'	System	23 Nov 2020 23:09:57
User entered '0'	System	23 Nov 2020 23:09:57

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-11-23T17:09:19', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'e7b650ed-4502-493e-acc2-ee96df1059e9'	System	23 Nov 2020 23:09:57
User entered '1'	System	23 Nov 2020 23:09:57

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-11-23T17:09:19', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'e7b650ed-4502-493e-acc2-ee96df1059e9'	System	23 Nov 2020 23:09:57
User entered '1'	System	23 Nov 2020 23:09:57

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-11-23T17:09:19', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'e7b650ed-4502-493e-acc2-ee96df1059e9'	System	23 Nov 2020 23:09:57
User entered '1'	System	23 Nov 2020 23:09:57

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

Muscle aches

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Muscle aches = Checked and Have you contacted a healthcare provider since last questionnaire or study contact? = Yes, however, please note that there is no corresponding AE for this recorded data. Please reconcile and update to record the AE as applicable, otherwise provide clarification. ' (Site from DM). Query 'Per DM CLR: Muscle aches = Checked and Have you contacted a healthcare provider since last questionnaire or study contact? = Yes, however, please note that there is no corresponding AE for this recorded data. Please reconcile and update to record the AE as applicable, otherwise provide clarification. ' answered with 'subject was never seen nor treated for muscle aches, never noted during illness visits or communications via telemed. ' (Site from DM).	(b) (4), (b) (6)	28 Dec 2020 20:19:45
User opened query 'Per DM CLR: Muscle aches = Checked and Have you contacted a healthcare provider since last questionnaire or study contact? = Yes, however, please note that there is no corresponding AE for this recorded data. Please reconcile and update to record the AE as applicable, otherwise provide clarification. ' (Site from DM).	Reagan Reed (b) (4)	18 Dec 2020 15:37:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-11-23T17:09:19', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'e7b650ed-4502-493e-acc2-ee96df1059e9'	(b) (4), (b) (6)	17 Dec 2020 03:30:35
User entered '1'	System	23 Nov 2020 23:09:57

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-11-23T17:09:19', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'e7b650ed-4502-493e-acc2-ee96df1059e9'	System	23 Nov 2020 23:09:57
User entered '0'	System	23 Nov 2020 23:09:57

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-11-23T17:09:19', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'e7b650ed-4502-493e-acc2-ee96df1059e9'	System	23 Nov 2020 23:09:57
User entered '1'	System	23 Nov 2020 23:09:57

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-11-23T17:09:19', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'e7b650ed-4502-493e-acc2-ee96df1059e9'	System	23 Nov 2020 23:09:57
User entered '0'	System	23 Nov 2020 23:09:57

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-11-23T17:09:19', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'e7b650ed-4502-493e-acc2-ee96df1059e9'	System	23 Nov 2020 23:09:57
User entered '0'	System	23 Nov 2020 23:09:57

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-11-23T17:09:19', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'e7b650ed-4502-493e-acc2-ee96df1059e9'	System	23 Nov 2020 23:09:57
User entered '0'	System	23 Nov 2020 23:09:57

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-11-23T17:09:19', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'e7b650ed-4502-493e-acc2-ee96df1059e9'	System	23 Nov 2020 23:09:57
User entered '0'	System	23 Nov 2020 23:09:57

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-11-23T17:09:19', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'e7b650ed-4502-493e-acc2-ee96df1059e9'	System	23 Nov 2020 23:09:57
User entered '0'	System	23 Nov 2020 23:09:57

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-11-23T17:09:19', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'e7b650ed-4502-493e-acc2-ee96df1059e9'	System	23 Nov 2020 23:09:57
User entered '0'	System	23 Nov 2020 23:09:57

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-11-23T17:09:19', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'e7b650ed-4502-493e-acc2-ee96df1059e9'	System	23 Nov 2020 23:09:57
User entered '0'	System	23 Nov 2020 23:09:57

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-11-23T17:09:19', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'e7b650ed-4502-493e-acc2-ee96df1059e9'	System	23 Nov 2020 23:09:57
User entered '1'	System	23 Nov 2020 23:09:57

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

Please 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 (b00d7c6802baa9d2)', Time: '2020-11-23T17:09:29', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'e7b650ed-4502-493e-acc2-ee96df1059e9'	System	23 Nov 2020 23:09:57
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	23 Nov 2020 23:09:57

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[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 (b00d7c6802baa9d2)', Time: '2020-11-23T17:09:34', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'e7b650ed-4502-493e-acc2-ee96df1059e9'	System	23 Nov 2020 23:09:57
User entered 'Yes (Y)'	System	23 Nov 2020 23:09:57

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

Please 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 (b00d7c6802baa9d2)', Time: '2020-11-23T17:09:38', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'e7b650ed-4502-493e-acc2-ee96df1059e9'	System	23 Nov 2020 23:09:57
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	23 Nov 2020 23:09:57

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-11-23T17:09:44', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'e7b650ed-4502-493e-acc2-ee96df1059e9' User entered '23 Nov 2020 17:09:44'	System	23 Nov 2020 23:09:57
	System	23 Nov 2020 23:09:57

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '22 Nov 2020 00:01'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '26 Nov 2020 23:59'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[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 (b00d7c6802baa9d2)', Time: '2020-11-29T17:08:52', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '4c31fe6e-d6c1-4db3-a1b0-245e63810875'	System	29 Nov 2020 23:09:06
User entered 'No (N)'	System	29 Nov 2020 23:09:06

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Have you been exposed to someone with 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 (b00d7c6802baa9d2)', Time: '2020-11-29T17:08:57', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '4c31fe6e-d6c1-4db3-a1b0-245e63810875'	System	29 Nov 2020 23:09:06
User entered 'No (N)'	System	29 Nov 2020 23:09:06

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-11-29T17:09:01', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '4c31fe6e-d6c1-4db3-a1b0-245e63810875'	System	29 Nov 2020 23:09:06
User entered '29 Nov 2020 17:09:01'	System	29 Nov 2020 23:09:06

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '29 Nov 2020 00:01'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '03 Dec 2020 23:59'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[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 (b00d7c6802baa9d2)', Time: '2020-12-08T12:16:26', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '813c1455-82cb-43b7-8e0e-b637f35b12c3'	System	08 Dec 2020 18:16:41
User entered 'No (N)'	System	08 Dec 2020 18:16:41

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Have you been exposed to someone with 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 (b00d7c6802baa9d2)', Time: '2020-12-08T12:16:29', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '813c1455-82cb-43b7-8e0e-b637f35b12c3'	System	08 Dec 2020 18:16:41
User entered 'No (N)'	System	08 Dec 2020 18:16:41

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-12-08T12:16:34', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '813c1455-82cb-43b7-8e0e-b637f35b12c3'	System	08 Dec 2020 18:16:41
User entered '08 Dec 2020 12:16:34'	System	08 Dec 2020 18:16:41

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '06 Dec 2020 00:01'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '10 Dec 2020 23:59'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[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 (b00d7c6802baa9d2)', Time: '2020-12-15T12:12:33', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'e00574a7-2af7-4efc-90f1-ca84b107d5b1'	System	15 Dec 2020 18:12:46
User entered 'No (N)'	System	15 Dec 2020 18:12:46

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Have you been exposed to someone with 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 (b00d7c6802baa9d2)', Time: '2020-12-15T12:12:36', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'e00574a7-2af7-4efc-90f1-ca84b107d5b1'	System	15 Dec 2020 18:12:46
User entered 'No (N)'	System	15 Dec 2020 18:12:46

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-12-15T12:12:40', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'e00574a7-2af7-4efc-90f1-ca84b107d5b1' User entered '15 Dec 2020 12:12:40'	System	15 Dec 2020 18:12:46
	System	15 Dec 2020 18:12:46

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '13 Dec 2020 00:01'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '17 Dec 2020 23:59'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[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 (b00d7c6802baa9d2)', Time: '2020-12-20T00:02:35', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '001cc30e-47d0-40d0-b839-5fa3c25adf47'	System	20 Dec 2020 06:02:54
User entered 'No (N)'	System	20 Dec 2020 06:02:54

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

Have you been exposed to someone with 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 (b00d7c6802baa9d2)', Time: '2020-12-20T00:02:38', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '001cc30e-47d0-40d0-b839-5fa3c25adf47'	System	20 Dec 2020 06:02:54
User entered 'No (N)'	System	20 Dec 2020 06:02:54

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-12-20T00:02:42', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '001cc30e-47d0-40d0-b839-5fa3c25adf47'	System	20 Dec 2020 06:02:54
User entered '20 Dec 2020 00:02:42'	System	20 Dec 2020 06:02:54

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '20 Dec 2020 00:01'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '24 Dec 2020 23:59'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[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 (b00d7c6802baa9d2)', Time: '2020-12-28T15:22:08', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '5fb326a1-91f6-4d5c-811c-517b47c09c18'	System	28 Dec 2020 21:22:18
User entered 'No (N)'	System	28 Dec 2020 21:22:18

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Have you been exposed to someone with 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 (b00d7c6802baa9d2)', Time: '2020-12-28T15:22:11', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '5fb326a1-91f6-4d5c-811c-517b47c09c18'	System	28 Dec 2020 21:22:18
User entered 'No (N)'	System	28 Dec 2020 21:22:18

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2020-12-28T15:22:14', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '5fb326a1-91f6-4d5c-811c-517b47c09c18'	System	28 Dec 2020 21:22:18
User entered '28 Dec 2020 15:22:14'	System	28 Dec 2020 21:22:18

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '27 Dec 2020 00:01'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '31 Dec 2020 23:59'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[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 (b00d7c6802baa9d2)', Time: '2021-01-03T02:48:36', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'ffc606e2-8cbd-4092-a2dc-c3b111a602f5'	System	03 Jan 2021 08:48:46
User entered 'No (N)'	System	03 Jan 2021 08:48:46

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

Have you been exposed to someone with 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 (b00d7c6802baa9d2)', Time: '2021-01-03T02:48:40', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'ffc606e2-8cbd-4092-a2dc-c3b111a602f5'	System	03 Jan 2021 08:48:46
User entered 'No (N)'	System	03 Jan 2021 08:48:46

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2021-01-03T02:48:43', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'ffc606e2-8cbd-4092-a2dc-c3b111a602f5'	System	03 Jan 2021 08:48:46
User entered '03 Jan 2021 02:48:43'	System	03 Jan 2021 08:48:46

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '03 Jan 2021 00:01'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '07 Jan 2021 23:59'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[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 (b00d7c6802baa9d2)', Time: '2021-01-14T11:11:30', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'dce3049e-b8a5-4e8c-818f-57633dfdce81'	System	14 Jan 2021 17:11:43
User entered 'No (N)'	System	14 Jan 2021 17:11:43

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Have you been exposed to someone with 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 (b00d7c6802baa9d2)', Time: '2021-01-14T11:11:33', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'dce3049e-b8a5-4e8c-818f-57633dfdce81'	System	14 Jan 2021 17:11:43
User entered 'No (N)'	System	14 Jan 2021 17:11:43

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2021-01-14T11:11:38', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'dce3049e-b8a5-4e8c-818f-57633dfdce81'	System	14 Jan 2021 17:11:43
User entered '14 Jan 2021 11:11:38'	System	14 Jan 2021 17:11:43

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '10 Jan 2021 00:01'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '14 Jan 2021 23:59'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[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 (b00d7c6802baa9d2)', Time: '2021-01-20T12:18:04', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'df28807d-1184-4f88-b11e-4dd5570530e7'	System	20 Jan 2021 18:18:18
User entered 'No (N)'	System	20 Jan 2021 18:18:18

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Have you been exposed to someone with 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 (b00d7c6802baa9d2)', Time: '2021-01-20T12:18:08', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'df28807d-1184-4f88-b11e-4dd5570530e7'	System	20 Jan 2021 18:18:18
User entered 'No (N)'	System	20 Jan 2021 18:18:18

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2021-01-20T12:18:12', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'df28807d-1184-4f88-b11e-4dd5570530e7' User entered '20 Jan 2021 12:18:12'	System	20 Jan 2021 18:18:18
	System	20 Jan 2021 18:18:18

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '17 Jan 2021 00:01'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '21 Jan 2021 23:59'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[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 (b00d7c6802baa9d2)', Time: '2021-01-24T02:01:17', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'd8daa157-49d7-4b59-ba15-1f22e2f51ffc'	System	24 Jan 2021 08:01:35
User entered 'No (N)'	System	24 Jan 2021 08:01:35

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

Have you been exposed to someone with 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 (b00d7c6802baa9d2)', Time: '2021-01-24T02:00:49', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'd8daa157-49d7-4b59-ba15-1f22e2f51ffc'	System	24 Jan 2021 08:01:35
User entered 'No (N)'	System	24 Jan 2021 08:01:35

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2021-01-24T02:01:31', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'd8daa157-49d7-4b59-ba15-1f22e2f51ffc'	System	24 Jan 2021 08:01:35
User entered '24 Jan 2021 02:01:31'	System	24 Jan 2021 08:01:35

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '24 Jan 2021 00:01'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '28 Jan 2021 23:59'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[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 (b00d7c6802baa9d2)', Time: '2021-01-31T14:24:46', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '40ac1061-e0dc-48f5-8223-6f5d5d1319ba'	System	31 Jan 2021 20:24:58
User entered 'No (N)'	System	31 Jan 2021 20:24:58

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

Have you been exposed to someone with 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 (b00d7c6802baa9d2)', Time: '2021-01-31T14:24:48', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '40ac1061-e0dc-48f5-8223-6f5d5d1319ba'	System	31 Jan 2021 20:24:58
User entered 'No (N)'	System	31 Jan 2021 20:24:58

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2021-01-31T14:24:52', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '40ac1061-e0dc-48f5-8223-6f5d5d1319ba'	System	31 Jan 2021 20:24:58
User entered '31 Jan 2021 14:24:52'	System	31 Jan 2021 20:24:58

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '31 Jan 2021 00:01'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '04 Feb 2021 23:59'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[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 (b00d7c6802baa9d2)', Time: '2021-02-10T11:55:10', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'da330817-2441-477e-b962-66106564cf66'	System	10 Feb 2021 17:55:25
User entered 'No (N)'	System	10 Feb 2021 17:55:25

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Have you been exposed to someone with 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 (b00d7c6802baa9d2)', Time: '2021-02-10T11:55:15', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'da330817-2441-477e-b962-66106564cf66'	System	10 Feb 2021 17:55:25
User entered 'No (N)'	System	10 Feb 2021 17:55:25

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2021-02-10T11:55:19', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'da330817-2441-477e-b962-66106564cf66'	System	10 Feb 2021 17:55:25
User entered '10 Feb 2021 11:55:19'	System	10 Feb 2021 17:55:25

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '07 Feb 2021 00:01'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '11 Feb 2021 23:59'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[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 (b00d7c6802baa9d2)', Time: '2021-02-14T00:01:25', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'b25ee1ad-885e-4f7b-ab22-fe1c67590f3b'	System	14 Feb 2021 06:01:52
User entered 'No (N)'	System	14 Feb 2021 06:01:52

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Have you been exposed to someone with 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 (b00d7c6802baa9d2)', Time: '2021-02-14T00:01:28', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'b25ee1ad-885e-4f7b-ab22-fe1c67590f3b'	System	14 Feb 2021 06:01:52
User entered 'No (N)'	System	14 Feb 2021 06:01:52

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2021-02-14T00:01:32', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'b25ee1ad-885e-4f7b-ab22-fe1c67590f3b'	System	14 Feb 2021 06:01:52
User entered '14 Feb 2021 00:01:32'	System	14 Feb 2021 06:01:52

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '14 Feb 2021 00:01'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '18 Feb 2021 23:59'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[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 (b00d7c6802baa9d2)', Time: '2021-02-24T22:28:48', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '0c0359aa-7183-4ecf-8910-3d85fbe222d0'	System	25 Feb 2021 04:29:02
User entered 'No (N)'	System	25 Feb 2021 04:29:02

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

Have you been exposed to someone with 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 (b00d7c6802baa9d2)', Time: '2021-02-24T22:28:52', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '0c0359aa-7183-4ecf-8910-3d85fbe222d0'	System	25 Feb 2021 04:29:02
User entered 'No (N)'	System	25 Feb 2021 04:29:02

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2021-02-24T22:28:55', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '0c0359aa-7183-4ecf-8910-3d85fbe222d0'	System	25 Feb 2021 04:29:02
User entered '24 Feb 2021 22:28:55'	System	25 Feb 2021 04:29:02

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '21 Feb 2021 00:01'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '25 Feb 2021 23:59'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[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 (b00d7c6802baa9d2)', Time: '2021-02-28T15:06:55-06:00', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'ed28592a-594e-41ee-93c4-20217eac8c60'	System	28 Feb 2021 21:07:04
User entered 'No (N)'	System	28 Feb 2021 21:07:04

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

Have you been exposed to someone with 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 (b00d7c6802baa9d2)', Time: '2021-02-28T15:06:58-06:00', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'ed28592a-594e-41ee-93c4-20217eac8c60'	System	28 Feb 2021 21:07:04
User entered 'No (N)'	System	28 Feb 2021 21:07:04

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2021-02-28T15:07:00-06:00', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'ed28592a-594e-41ee-93c4-20217eac8c60'	System	28 Feb 2021 21:07:04
User entered '28 Feb 2021 15:07:00'	System	28 Feb 2021 21:07:04

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '28 Feb 2021 00:01'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '04 Mar 2021 23:59'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[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 (b00d7c6802baa9d2)', Time: '2021-03-09T11:33:06-06:00', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '30c2f319-e584-40e1-9817-140da6341c72'	System	09 Mar 2021 17:33:42
User entered 'No (N)'	System	09 Mar 2021 17:33:42

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

Have you been exposed to someone with 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 (b00d7c6802baa9d2)', Time: '2021-03-09T11:33:09-06:00', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '30c2f319-e584-40e1-9817-140da6341c72'	System	09 Mar 2021 17:33:42
User entered 'No (N)'	System	09 Mar 2021 17:33:42

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2021-03-09T11:33:13-06:00', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '30c2f319-e584-40e1-9817-140da6341c72'	System	09 Mar 2021 17:33:42
User entered '09 Mar 2021 11:33:13'	System	09 Mar 2021 17:33:42

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '07 Mar 2021 00:01'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '11 Mar 2021 23:59'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[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 (b00d7c6802baa9d2)', Time: '2021-03-15T11:11:00-05:00', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '8c48adde-3b97-481d-900e-b90bf97f6244'	System	15 Mar 2021 16:18:25
User entered 'No (N)'	System	15 Mar 2021 16:18:25

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

Have you been exposed to someone with 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 (b00d7c6802baa9d2)', Time: '2021-03-15T11:11:05-05:00', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '8c48adde-3b97-481d-900e-b90bf97f6244'	System	15 Mar 2021 16:18:25
User entered 'No (N)'	System	15 Mar 2021 16:18:25

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2021-03-15T11:11:08-05:00', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '8c48adde-3b97-481d-900e-b90bf97f6244'	System	15 Mar 2021 16:18:25
User entered '15 Mar 2021 11:11:08'	System	15 Mar 2021 16:18:25

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '14 Mar 2021 00:01'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '18 Mar 2021 23:59'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[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 (b00d7c6802baa9d2)', Time: '2021-03-25T10:15:41-05:00', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'e344797a-e123-44c1-b680-52b724a8b2a9'	System	25 Mar 2021 15:15:54
User entered 'No (N)'	System	25 Mar 2021 15:15:54

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

Have you been exposed to someone with 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 (b00d7c6802baa9d2)', Time: '2021-03-25T10:15:45-05:00', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'e344797a-e123-44c1-b680-52b724a8b2a9'	System	25 Mar 2021 15:15:54
User entered 'No (N)'	System	25 Mar 2021 15:15:54

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2021-03-25T10:15:49-05:00', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'e344797a-e123-44c1-b680-52b724a8b2a9'	System	25 Mar 2021 15:15:54
User entered '25 Mar 2021 10:15:49'	System	25 Mar 2021 15:15:54

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '21 Mar 2021 00:01'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '25 Mar 2021 23:59'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[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 (b00d7c6802baa9d2)', Time: '2021-03-29T17:48:26-05:00', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '50ed3cad-0863-4844-9cf0-070179531e1d'	System	29 Mar 2021 22:48:39
User entered 'No (N)'	System	29 Mar 2021 22:48:39

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

Have you been exposed to someone with 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 (b00d7c6802baa9d2)', Time: '2021-03-29T17:48:29-05:00', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '50ed3cad-0863-4844-9cf0-070179531e1d'	System	29 Mar 2021 22:48:39
User entered 'No (N)'	System	29 Mar 2021 22:48:39

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2021-03-29T17:48:32-05:00', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '50ed3cad-0863-4844-9cf0-070179531e1d' User entered '29 Mar 2021 17:48:32'	System	29 Mar 2021 22:48:39
	System	29 Mar 2021 22:48:39

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '28 Mar 2021 00:01'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '01 Apr 2021 23:59'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[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 (b00d7c6802baa9d2)', Time: '2021-04-04T08:48:08-05:00', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '0874b1cf-4498-44d0-afed-3b358b943cfd' User entered 'No (N)'	System	04 Apr 2021 13:48:18
	System	04 Apr 2021 13:48:18

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

Have you been exposed to someone with 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 (b00d7c6802baa9d2)', Time: '2021-04-04T08:48:11-05:00', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '0874b1cf-4498-44d0-afed-3b358b943cfd'	System	04 Apr 2021 13:48:18
User entered 'No (N)'	System	04 Apr 2021 13:48:18

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2021-04-04T08:48:15-05:00', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '0874b1cf-4498-44d0-afed-3b358b943cfd'	System	04 Apr 2021 13:48:18
User entered '04 Apr 2021 08:48:15'	System	04 Apr 2021 13:48:18

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '04 Apr 2021 00:01'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '08 Apr 2021 23:59'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[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 (b00d7c6802baa9d2)', Time: '2021-04-15T11:14:50-05:00', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '3e50057b-c304-4dfc-80dd-9b72065a1282' User entered 'No (N)'	System	15 Apr 2021 16:18:42
	System	15 Apr 2021 16:18:42

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

Have you been exposed to someone with 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 (b00d7c6802baa9d2)', Time: '2021-04-15T11:14:53-05:00', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '3e50057b-c304-4dfc-80dd-9b72065a1282' User entered 'No (N)'	System	15 Apr 2021 16:18:42
	System	15 Apr 2021 16:18:42

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2021-04-15T11:14:56-05:00', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '3e50057b-c304-4dfc-80dd-9b72065a1282'	System	15 Apr 2021 16:18:42
User entered '15 Apr 2021 11:14:56'	System	15 Apr 2021 16:18:42

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '11 Apr 2021 00:01'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '15 Apr 2021 23:59'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '18 Apr 2021 00:01'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '22 Apr 2021 23:59'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[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 (b00d7c6802baa9d2)', Time: '2021-04-26T14:30:03-05:00', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '94054b0e-a3e0-45b8-91fe-877337787e27'	System	26 Apr 2021 19:30:13
User entered 'No (N)'	System	26 Apr 2021 19:30:13

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

Have you been exposed to someone with 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 (b00d7c6802baa9d2)', Time: '2021-04-26T14:30:07-05:00', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '94054b0e-a3e0-45b8-91fe-877337787e27'	System	26 Apr 2021 19:30:13
User entered 'No (N)'	System	26 Apr 2021 19:30:13

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2021-04-26T14:30:10-05:00', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: '94054b0e-a3e0-45b8-91fe-877337787e27' User entered '26 Apr 2021 14:30:10'	System	26 Apr 2021 19:30:13
	System	26 Apr 2021 19:30:13

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '25 Apr 2021 00:01'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '29 Apr 2021 23:59'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '02 May 2021 00:01'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '06 May 2021 23:59'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '09 May 2021 00:01'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '13 May 2021 23:59'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '16 May 2021 00:01'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '20 May 2021 23:59'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '23 May 2021 00:01'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '27 May 2021 23:59'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '30 May 2021 00:01'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '03 Jun 2021 23:59'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '06 Jun 2021 00:01'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '10 Jun 2021 23:59'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '13 Jun 2021 00:01'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '17 Jun 2021 23:59'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '20 Jun 2021 00:01'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '24 Jun 2021 23:59'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '27 Jun 2021 00:01'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '01 Jul 2021 23:59'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '04 Jul 2021 00:01'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '08 Jul 2021 23:59'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '11 Jul 2021 00:01'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '15 Jul 2021 23:59'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '18 Jul 2021 00:01'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '22 Jul 2021 23:59'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '25 Jul 2021 00:01'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '29 Jul 2021 23:59'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '01 Aug 2021 00:01'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '05 Aug 2021 23:59'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '08 Aug 2021 00:01'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '12 Aug 2021 23:59'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '15 Aug 2021 00:01'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '19 Aug 2021 23:59'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '22 Aug 2021 00:01'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '26 Aug 2021 23:59'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '29 Aug 2021 00:01'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '02 Sep 2021 23:59'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '05 Sep 2021 00:01'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '09 Sep 2021 23:59'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '12 Sep 2021 00:01'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '16 Sep 2021 23:59'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '19 Sep 2021 00:01'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '23 Sep 2021 23:59'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '26 Sep 2021 00:01'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '30 Sep 2021 23:59'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '03 Oct 2021 00:01'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '07 Oct 2021 23:59'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '10 Oct 2021 00:01'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '14 Oct 2021 23:59'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '17 Oct 2021 00:01'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '21 Oct 2021 23:59'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '24 Oct 2021 00:01'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '28 Oct 2021 23:59'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '31 Oct 2021 00:01'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '04 Nov 2021 23:59'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '07 Nov 2021 00:01'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '11 Nov 2021 23:59'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '14 Nov 2021 00:01'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '18 Nov 2021 23:59'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '21 Nov 2021 00:01'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '25 Nov 2021 23:59'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '28 Nov 2021 00:01'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '02 Dec 2021 23:59'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '05 Dec 2021 00:01'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '09 Dec 2021 23:59'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '12 Dec 2021 00:01'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '16 Dec 2021 23:59'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '19 Dec 2021 00:01'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '23 Dec 2021 23:59'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '26 Dec 2021 00:01'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '30 Dec 2021 23:59'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '02 Jan 2022 00:01'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '06 Jan 2022 23:59'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '09 Jan 2022 00:01'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '13 Jan 2022 23:59'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '16 Jan 2022 00:01'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '20 Jan 2022 23:59'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '23 Jan 2022 00:01'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '27 Jan 2022 23:59'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '30 Jan 2022 00:01'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '03 Feb 2022 23:59'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '06 Feb 2022 00:01'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '10 Feb 2022 23:59'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '13 Feb 2022 00:01'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '17 Feb 2022 23:59'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '20 Feb 2022 00:01'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '24 Feb 2022 23:59'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '27 Feb 2022 00:01'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '03 Mar 2022 23:59'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '06 Mar 2022 00:01'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '10 Mar 2022 23:59'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '13 Mar 2022 00:01'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '17 Mar 2022 23:59'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '20 Mar 2022 00:01'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '24 Mar 2022 23:59'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '27 Mar 2022 00:01'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '31 Mar 2022 23:59'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '03 Apr 2022 00:01'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '07 Apr 2022 23:59'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '10 Apr 2022 00:01'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '14 Apr 2022 23:59'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '17 Apr 2022 00:01'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '21 Apr 2022 23:59'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '24 Apr 2022 00:01'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '28 Apr 2022 23:59'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '01 May 2022 00:01'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '05 May 2022 23:59'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '08 May 2022 00:01'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '12 May 2022 23:59'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '15 May 2022 00:01'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '19 May 2022 23:59'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '22 May 2022 00:01'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '26 May 2022 23:59'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '29 May 2022 00:01'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '02 Jun 2022 23:59'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '05 Jun 2022 00:01'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '09 Jun 2022 23:59'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '12 Jun 2022 00:01'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '16 Jun 2022 23:59'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '19 Jun 2022 00:01'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '23 Jun 2022 23:59'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '26 Jun 2022 00:01'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '30 Jun 2022 23:59'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '03 Jul 2022 00:01'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '07 Jul 2022 23:59'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '10 Jul 2022 00:01'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '14 Jul 2022 23:59'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '17 Jul 2022 00:01'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '21 Jul 2022 23:59'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '24 Jul 2022 00:01'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '28 Jul 2022 23:59'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '31 Jul 2022 00:01'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '04 Aug 2022 23:59'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '07 Aug 2022 00:01'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '11 Aug 2022 23:59'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '14 Aug 2022 00:01'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '18 Aug 2022 23:59'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '21 Aug 2022 00:01'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '25 Aug 2022 23:59'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '28 Aug 2022 00:01'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '01 Sep 2022 23:59'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '04 Sep 2022 00:01'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '08 Sep 2022 23:59'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '11 Sep 2022 00:01'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '15 Sep 2022 23:59'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '18 Sep 2022 00:01'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '22 Sep 2022 23:59'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '25 Sep 2022 00:01'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '29 Sep 2022 23:59'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '02 Oct 2022 00:01'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '06 Oct 2022 23:59'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '09 Oct 2022 00:01'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '13 Oct 2022 23:59'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '16 Oct 2022 00:01'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '20 Oct 2022 23:59'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '23 Oct 2022 00:01'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '27 Oct 2022 23:59'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '30 Oct 2022 00:01'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '03 Nov 2022 23:59'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '06 Nov 2022 00:01'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '10 Nov 2022 23:59'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '13 Nov 2022 00:01'	System	20 Nov 2020 07:53:29

US3212394

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:51:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:53:29
Amendment Manager: User entered '17 Nov 2022 23:59'	System	20 Nov 2020 07:53:29

US3212394

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:51:18

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2021-02-28T15:07:09-06:00', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'c2ce75ff-f9df-4b5f-bd7a-ba1ffda9e3f5'	System	28 Feb 2021 21:07:24
User entered 'No (N)'	System	28 Feb 2021 21:07:24

US3212394

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:51:18

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b00d7c6802baa9d2)', Time: '2021-02-28T15:07:22-06:00', User OID: 'PatientReportedOutcome (US3212394)', ODM File OID: 'c2ce75ff-f9df-4b5f-bd7a-ba1ffda9e3f5'	System	28 Feb 2021 21:07:24
User entered '28 Feb 2021 15:07:22'	System	28 Feb 2021 21:07:24

US3212394

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:51:18

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:27
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 21:42:50
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	09 Dec 2020 15:07:00

US3212394

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:51:18

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:27
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 21:42:50
User entered '10 Dec 2020' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	22 Dec 2020 17:30:47
User entered '08 Dec 2020'	Laura Ngansop Djampou (b) (4)	09 Dec 2020 15:07:00

US3212394

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:51:18

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:27
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 21:42:50
User entered 'Contact Made (CONTACT MADE)' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	22 Dec 2020 17:30:47
User entered 'Contact Not Made (CONTACT NOT MADE)'	Laura Ngansop Djampou (b) (4)	09 Dec 2020 15:07:00

US3212394

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:51:18

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:27
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 21:42:50
User entered empty; reason for change Data Entry Error	Laura Ngansop Djampou (b) (4)	22 Dec 2020 17:30:47
User entered 'Called for day 85, no answer, left a voicemail'	Laura Ngansop Djampou (b) (4)	09 Dec 2020 15:07:00

US3212394

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:51:18

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:27
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 21:42:56
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	09 Dec 2020 15:07:04

US3212394

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:51:18

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:08:27
User entered 'I'	System	09 Dec 2020 15:07:04

US3212394

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:51:18

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:52:36
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:38:49
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	12 Jan 2021 14:43:16

US3212394

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:51:18

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:52:36
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:38:49
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered '11 Jan 2021'	Laura Ngansop Djampou (b) (4)	12 Jan 2021 14:43:16

US3212394

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:51:18

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:52:36
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:38:49
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'Contact Made (CONTACT MADE)'	Laura Ngansop Djampou (b) (4)	12 Jan 2021 14:43:16

US3212394

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:51:18

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:52:36
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:38:49
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Laura Ngansop Djampou (b) (4)	12 Jan 2021 14:43:16

US3212394

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:51:18

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:52:36
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:39:01
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	12 Jan 2021 14:43:20

US3212394

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:51:18

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:52:36
User entered 'I'	System	12 Jan 2021 14:43:20

US3212394

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:51:18

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:52:36
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:39:15
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	09 Feb 2021 20:18:12

US3212394

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:51:18

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:52:36
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:39:15
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered '08 Feb 2021'	Laura Ngansop Djampou (b) (4)	09 Feb 2021 20:18:12

US3212394

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:51:18

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:52:36
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:39:15
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'Contact Made (CONTACT MADE)'	Laura Ngansop Djampou (b) (4)	09 Feb 2021 20:18:12

US3212394

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:51:18

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:52:36
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:39:15
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Laura Ngansop Djampou (b) (4)	09 Feb 2021 20:18:12

US3212394

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:51:18

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:52:36
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:40:31
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	09 Feb 2021 20:17:58

US3212394

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:51:18

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:52:36
User entered 'I'	System	09 Feb 2021 20:17:58

US3212394

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:51:18

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:52:36
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:41:42
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	11 Mar 2021 16:19:33

US3212394

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:51:18

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:52:36
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:16:25
DataPoint Verified.	(b) (4)	16 Apr 2021 17:55:07
User closed query 'Per source, call was completed 12Mar21. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 17:54:54
Query 'Per source, call was completed 12Mar21. Please verify and update accordingly.' answered with 'updated' (Site from CRA).	Heather Leary (b) (4)	16 Apr 2021 13:30:20
Signature has been broken.	(b) (4)	16 Apr 2021 13:28:27
User entered '12 Mar 2021' reason for change: Data Entry Error	Heather Leary (b) (4)	16 Apr 2021 13:28:27
User opened query 'Per source, call was completed 12Mar21. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 05:41:39
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered '10 Mar 2021'	Laura Ngansop Djampou (b) (4)	11 Mar 2021 16:19:33

US3212394

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:51:18

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:52:36
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:41:44
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'Contact Made (CONTACT MADE)' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	17 Mar 2021 15:56:07
User entered 'Contact Not Made (CONTACT NOT MADE)'	Laura Ngansop Djampou (b) (4)	11 Mar 2021 16:19:33

US3212394

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:51:18

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:52:36
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:41:48
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty; reason for change Data Entry Error	Laura Ngansop Djampou (b) (4)	17 Mar 2021 15:56:07
User entered 'attempted contact, no response'	Laura Ngansop Djampou (b) (4)	11 Mar 2021 16:19:33

US3212394

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:51:18

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:52:36
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:41:54
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	11 Mar 2021 16:19:38

US3212394

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:51:18

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:52:36
User entered 'I'	System	11 Mar 2021 16:19:38

US3212394

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:51:18

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:16:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 05:42:33
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Apr 2021 15:21:19

US3212394

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:51:18

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

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:16:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 05:42:33
User entered '09 Apr 2021'	(b) (4), (b) (6)	12 Apr 2021 15:21:19

US3212394

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:51:18

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

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:16:31
DataPoint Verified.	(b) (4)	16 Apr 2021 05:42:33
	(b) (4), (b) (6)	
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	12 Apr 2021 15:21:19

US3212394

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:51:18

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT4'	System	12 Apr 2021 15:21:19

US3212394

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:51:18

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:16:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 05:42:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Apr 2021 15:22:27

US3212394

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:51:18

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:16:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 05:42:47
User entered '9 Apr 2021'	(b) (4), (b) (6)	12 Apr 2021 15:22:27

US3212394

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:51:18

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

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:16:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 05:42:47
User entered '14:15'	(b) (4), (b) (6)	12 Apr 2021 15:22:27

US3212394

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:51:18

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

Audit	User	Time (GMT)
User entered '9 Apr 2021 14:15'	System	12 Apr 2021 15:22:27

US3212394

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:51:18

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

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:16:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 05:42:47
User entered '97.9' F	(b) (4), (b) (6)	12 Apr 2021 15:22:27

US3212394

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:51:18

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:16:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 05:42:47
User entered 'Oral (Oral)'	(b) (4), (b) (6)	12 Apr 2021 15:22:27

US3212394

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:51:18

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:16:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 05:42:47
User entered empty.	(b) (4), (b) (6)	12 Apr 2021 15:22:27

US3212394

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:51:18

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:16:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 05:42:47
User entered '92'	(b) (4), (b) (6)	12 Apr 2021 15:22:27

US3212394

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:51:18

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	12 Apr 2021 15:22:27

US3212394

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:51:18

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

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:16:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 05:42:47
User entered '17'	(b) (4), (b) (6)	12 Apr 2021 15:22:27

US3212394

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:51:18

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	12 Apr 2021 15:22:27

US3212394

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:51:18

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

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:16:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 05:42:47
User entered '118'	(b) (4), (b) (6)	12 Apr 2021 15:22:27

US3212394

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:51:18

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	12 Apr 2021 15:22:27

US3212394

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:51:18

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

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:16:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 05:42:47
User entered '80'	(b) (4), (b) (6)	12 Apr 2021 15:22:27

US3212394

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:51:18

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	12 Apr 2021 15:22:27

US3212394

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:51:18

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:16:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 05:42:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Apr 2021 15:22:49

US3212394

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:51:18

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:16:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 05:42:52
User entered '09 Apr 2021'	(b) (4), (b) (6)	12 Apr 2021 15:22:49

US3212394

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:51:18

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:16:25
DataPoint Verified.	(b) (4)	16 Apr 2021 05:42:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Apr 2021 15:23:13

US3212394

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:51:18

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:16:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 05:42:57
User entered '09 Apr 2021'	(b) (4), (b) (6)	12 Apr 2021 15:23:13

US3212394

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:51:18

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:16:25
DataPoint Verified.	(b) (4)	16 Apr 2021 05:42:57
	(b) (4), (b) (6)	
User entered '14:31'	(b) (4), (b) (6)	12 Apr 2021 15:23:13

US3212394

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:51:18

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '09 Apr 2021 14:31'	System	12 Apr 2021 15:23:13

US3212394

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:51:18

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:16:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 05:43:02
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Apr 2021 15:23:27

US3212394

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:51:18

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Apr 2021 15:23:27

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:51:18

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:18
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered '25 Nov 2020'	Afifah Ayub (b) (4) (b) (4)	30 Nov 2020 10:20:57

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:51:18

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:18
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered '13:25'	Afifah Ayub (b) (4)	30 Nov 2020 10:20:57

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:51:18

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:23
User entered '25 Nov 2020 13:25'	System	30 Nov 2020 10:20:57

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:51:18

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:18
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)'	Afifah Ayub (b) (4)	30 Nov 2020 10:20:57

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:51:18

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:18
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	30 Nov 2020 10:20:57

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:51:18

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'Day 1 (Day 1)'	Afifah Ayub (b) (4)	30 Nov 2020 10:22:49

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:51:18

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:52:48
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered '13 Nov 2020'	Afifah Ayub (b) (4)	30 Nov 2020 10:22:49

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:51:18

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:52:48
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered '0'	Afifah Ayub (b) (4)	30 Nov 2020 10:22:49

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:51:18

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:52:48
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered missing code ND - Not Done.	Afifah Ayub (b) (4)	30 Nov 2020 10:22:49

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:51:18

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
User entered '%'	System	30 Nov 2020 10:22:49

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:51:18

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:52:48
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered missing code ND - Not Done.	Afifah Ayub (b) (4)	30 Nov 2020 10:22:49

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:51:18

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:52:48
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'None (None)'	Afifah Ayub (b) (4)	30 Nov 2020 10:22:49

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:51:18

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:52:48
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'None (None)'	Afifah Ayub (b) (4)	30 Nov 2020 10:22:49

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:51:18

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:52:21
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'Moderate (Moderate)'	Afifah Ayub (b) (4)	30 Nov 2020 10:22:49

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:51:18

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:52:48
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'None (None)'	Afifah Ayub (b) (4)	30 Nov 2020 10:22:49

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:51:18

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:52:26
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'Moderate (Moderate)'	Afifah Ayub (b) (4)	30 Nov 2020 10:22:49

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:51:18

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:52:48
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'None (None)'	Afifah Ayub (b) (4)	30 Nov 2020 10:22:49

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:51:18

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:52:48
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'None (None)'	Afifah Ayub (b) (4)	30 Nov 2020 10:22:49

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:51:18

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:52:31
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'Moderate (Moderate)'	Afifah Ayub (b) (4)	30 Nov 2020 10:22:49

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:51:18

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:52:48
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'None (None)'	Afifah Ayub (b) (4)	30 Nov 2020 10:22:49

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:51:18

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:52:48
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'None (None)'	Afifah Ayub (b) (4)	30 Nov 2020 10:22:49

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:51:18

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:52:48
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'None (None)'	Afifah Ayub (b) (4)	30 Nov 2020 10:22:49

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:51:18

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:52:48
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'None (None)'	Afifah Ayub (b) (4)	30 Nov 2020 10:22:49

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:51:18

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:52:48
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'None (None)'	Afifah Ayub (b) (4)	30 Nov 2020 10:22:49

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:51:18

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:52:48
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'None (None)'	Afifah Ayub (b) (4)	30 Nov 2020 10:22:49

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:51:18

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:52:48
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'None (None)'	Afifah Ayub (b) (4)	30 Nov 2020 10:22:49

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:51:18

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:52:48
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'None (None)'	Afifah Ayub (b) (4)	30 Nov 2020 10:22:49

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:51:18

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'Day 2 (Day 2)'	Afifah Ayub (b) (4)	30 Nov 2020 10:22:59

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:51:18

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:33
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered '14 Nov 2020'	Atifah Ayub (b) (4)	30 Nov 2020 10:22:59

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:51:18

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:33
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'I'	Afifah Ayub (b) (4)	30 Nov 2020 10:22:59

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:51:18

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:33
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:22:59

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:51:18

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
User entered empty.	System	30 Nov 2020 10:22:59

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:51:18

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:33
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:22:59

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:51:18

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:33
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:22:59

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:51:18

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:33
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:22:59

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:51:18

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:33
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:22:59

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:51:18

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:33
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:22:59

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:51:18

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:33
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:22:59

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:51:18

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:33
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:22:59

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:51:18

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:33
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:22:59

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:51:18

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:33
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:22:59

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:51:18

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:33
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:22:59

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:51:18

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:33
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:22:59

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:51:18

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:33
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:22:59

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:51:18

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:33
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:22:59

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:51:18

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:33
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:22:59

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:51:18

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:33
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:22:59

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:51:18

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:33
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:22:59

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:51:18

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:33
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:22:59

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:51:18

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'Day 3 (Day 3)'	Afifah Ayub (b) (4)	30 Nov 2020 10:23:14

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:51:18

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:36
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered '15 Nov 2020'	Afifah Ayub (b) (4)	30 Nov 2020 10:23:14

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:51:18

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:36
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'I'	Afifah Ayub (b) (4)	30 Nov 2020 10:23:14

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:51:18

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:36
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4) (b) (4)	30 Nov 2020 10:23:14

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:51:18

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
User entered empty.	System	30 Nov 2020 10:23:14

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:51:18

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:36
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:23:14

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:51:18

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:36
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:23:14

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:51:18

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:36
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:23:14

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:51:18

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:36
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:23:14

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:51:18

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:36
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:23:14

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:51:18

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:36
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:23:14

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:51:18

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:36
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:23:14

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:51:18

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:36
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:23:14

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:51:18

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:36
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:23:14

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:51:18

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:36
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:23:14

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:51:18

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:36
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:23:14

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:51:18

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:36
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:23:14

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:51:18

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:36
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:23:14

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:51:18

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:36
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:23:14

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:51:18

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:36
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:23:14

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:51:18

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:36
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:23:14

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:51:18

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:36
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:23:14

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:51:18

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'Day 4 (Day 4)'	Afifah Ayub (b) (4)	30 Nov 2020 10:23:21

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:51:18

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:38
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered '16 Nov 2020'	Afifah Ayub (b) (4)	30 Nov 2020 10:23:21

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:51:18

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:38
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'I'	Afifah Ayub (b) (4)	30 Nov 2020 10:23:21

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:51:18

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:38
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:23:21

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:51:18

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
User entered empty.	System	30 Nov 2020 10:23:21

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:51:18

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:38
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:23:21

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:51:18

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:38
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:23:21

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:51:18

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:38
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:23:21

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:51:18

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:38
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:23:21

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:51:18

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:38
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:23:21

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:51:18

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:38
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:23:21

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:51:18

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:38
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:23:21

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:51:18

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:38
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:23:21

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:51:18

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:38
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Atifah Ayub (b) (4)	30 Nov 2020 10:23:21

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:51:18

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:38
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:23:21

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:51:18

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:38
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:23:21

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:51:18

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:38
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:23:21

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:51:18

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:38
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:23:21

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:51:18

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:38
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:23:21

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:51:18

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:38
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:23:21

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:51:18

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:38
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:23:21

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:51:18

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:38
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:23:21

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:51:18

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'Day 5 (Day 5)'	Afifah Ayub (b) (4)	30 Nov 2020 10:23:31

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:51:18

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:39
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered '17 Nov 2020'	Atifah Ayub (b) (4)	30 Nov 2020 10:23:31

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:51:18

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:39
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'I'	Atifah Ayub (b) (4)	30 Nov 2020 10:23:31

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:51:18

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:39
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:23:31

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:51:18

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
User entered empty.	System	30 Nov 2020 10:23:31

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:51:18

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:39
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:23:31

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:51:18

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:39
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:23:31

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:51:18

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:39
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:23:31

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:51:18

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:39
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:23:31

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:51:18

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:39
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:23:31

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:51:18

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:39
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:23:31

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:51:18

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:39
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:23:31

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:51:18

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:39
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4) (b) (4)	30 Nov 2020 10:23:31

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:51:18

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:39
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:23:31

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:51:18

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:39
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:23:31

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:51:18

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:39
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:23:31

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:51:18

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:39
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:23:31

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:51:18

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:39
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:23:31

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:51:18

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:39
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:23:31

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:51:18

Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:39
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:23:31

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:51:18

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:39
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:23:31

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:51:18

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:39
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:23:31

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:51:18

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'Day 6 (Day 6)'	Afifah Ayub (b) (4)	30 Nov 2020 10:23:50

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:51:18

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:41
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered '18 Nov 2020'	Atifah Ayub (b) (4)	30 Nov 2020 10:23:50

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:51:18

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:41
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'I'	Afifah Ayub (b) (4)	30 Nov 2020 10:23:50

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:51:18

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:41
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:23:50

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:51:18

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
User entered empty.	System	30 Nov 2020 10:23:50

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:51:18

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:41
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:23:50

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:51:18

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:41
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:23:50

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:51:18

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:41
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:23:50

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:51:18

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:41
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:23:50

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:51:18

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:41
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:23:50

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:51:18

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:41
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:23:50

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:51:18

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:41
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:23:50

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:51:18

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:41
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:23:50

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:51:18

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:41
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:23:50

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:51:18

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:41
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:23:50

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:51:18

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:41
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:23:50

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:51:18

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:41
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:23:50

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:51:18

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:41
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:23:50

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:51:18

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:41
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4) (b) (4)	30 Nov 2020 10:23:50

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:51:18

Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:41
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4) (b) (4)	30 Nov 2020 10:23:50

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:51:18

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:41
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:23:50

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:51:18

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:41
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:23:50

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:51:18

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'Day 7 (Day 7)'	Afifah Ayub (b) (4)	30 Nov 2020 10:23:59

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:51:18

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:43
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered '19 Nov 2020'	Afifah Ayub (b) (4)	30 Nov 2020 10:23:59

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:51:18

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:43
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'I'	Afifah Ayub (b) (4)	30 Nov 2020 10:23:59

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:51:18

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:43
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:23:59

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:51:18

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
User entered empty.	System	30 Nov 2020 10:23:59

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:51:18

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:43
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:23:59

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:51:18

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:43
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:23:59

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:51:18

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:43
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:23:59

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:51:18

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:43
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:23:59

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:51:18

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:43
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:23:59

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:51:18

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:43
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:23:59

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:51:18

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:43
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:23:59

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:51:18

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:43
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:23:59

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:51:18

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:43
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:23:59

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:51:18

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:43
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:23:59

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:51:18

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:43
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Atifah Ayub (b) (4)	30 Nov 2020 10:23:59

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:51:18

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:43
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Atifah Ayub (b) (4)	30 Nov 2020 10:23:59

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:51:18

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:43
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:23:59

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:51:18

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:43
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:23:59

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:51:18

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:43
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:23:59

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:51:18

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:43
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:23:59

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:51:18

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:43
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:23:59

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:51:18

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'Day 8 (Day 8)'	Afifah Ayub (b) (4)	30 Nov 2020 10:24:10

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:51:18

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:44
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered '20 Nov 2020'	Atifah Ayub (b) (4)	30 Nov 2020 10:24:10

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:51:18

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:44
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'I'	Afifah Ayub (b) (4)	30 Nov 2020 10:24:10

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:51:18

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:44
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:24:10

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:51:18

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
User entered empty.	System	30 Nov 2020 10:24:10

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:51:18

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:44
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:24:10

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:51:18

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:44
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:24:10

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:51:18

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:44
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:24:10

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:51:18

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:44
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Atifah Ayub (b) (4)	30 Nov 2020 10:24:10

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:51:18

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:44
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:24:10

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:51:18

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:44
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:24:10

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:51:18

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:44
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:24:10

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:51:18

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:44
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:24:10

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:51:18

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:44
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:24:10

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:51:18

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:44
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:24:10

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:51:18

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:44
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:24:10

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:51:18

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:44
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:24:10

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:51:18

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:44
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:24:10

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:51:18

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:44
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:24:10

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:51:18

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:44
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:24:10

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:51:18

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:44
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:24:10

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:51:18

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:44
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:24:10

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:51:18

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'Day 9 (Day 9)'	Afifah Ayub (b) (4)	30 Nov 2020 10:24:18

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:51:18

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:48
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered '21 Nov 2020'	Afifah Ayub (b) (4)	30 Nov 2020 10:24:18

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:51:18

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:48
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'I'	Afifah Ayub (b) (4) (b) (4)	30 Nov 2020 10:24:18

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:51:18

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:48
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:24:18

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:51:18

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
User entered empty.	System	30 Nov 2020 10:24:18

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:51:18

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:48
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Atifah Ayub (b) (4)	30 Nov 2020 10:24:18

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:51:18

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:48
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:24:18

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:51:18

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:48
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:24:18

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:51:18

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:48
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:24:18

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:51:18

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:48
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:24:18

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:51:18

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:48
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:24:18

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:51:18

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:48
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:24:18

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:51:18

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:48
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:24:18

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:51:18

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:48
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:24:18

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:51:18

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:48
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:24:18

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:51:18

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:48
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:24:18

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:51:18

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:48
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:24:18

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:51:18

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:48
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:24:18

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:51:18

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:48
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4) (b) (4)	30 Nov 2020 10:24:18

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:51:18

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:48
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:24:18

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:51:18

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:48
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4) (b) (4)	30 Nov 2020 10:24:18

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:51:18

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:48
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:24:18

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:51:18

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'Day 10 (Day 10)'	Afifah Ayub (b) (4)	30 Nov 2020 10:24:28

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:51:18

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:49
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered '22 Nov 2020'	Atifah Ayub (b) (4)	30 Nov 2020 10:24:28

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:51:18

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:49
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'I'	Atifah Ayub (b) (4)	30 Nov 2020 10:24:28

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:51:18

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:49
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:24:28

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:51:18

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
User entered empty.	System	30 Nov 2020 10:24:28

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:51:18

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:49
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:24:28

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:51:18

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:49
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:24:28

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:51:18

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:49
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:24:28

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:51:18

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:49
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:24:28

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:51:18

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:49
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:24:28

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:51:18

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:49
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4) (b) (4)	30 Nov 2020 10:24:28

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:51:18

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:49
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:24:28

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:51:18

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:49
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:24:28

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:51:18

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:49
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:24:28

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:51:18

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:49
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:24:28

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:51:18

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:49
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:24:28

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:51:18

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:49
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:24:28

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:51:18

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:49
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:24:28

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:51:18

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:49
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Atifah Ayub (b) (4)	30 Nov 2020 10:24:28

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:51:18

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:49
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:24:28

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:51:18

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:49
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:24:28

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:51:18

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:49
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:24:28

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:51:18

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'Day 11 (Day 11)'	Afifah Ayub (b) (4)	30 Nov 2020 10:24:38

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:51:18

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:51
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered '23 Nov 2020'	Afifah Ayub (b) (4)	30 Nov 2020 10:24:38

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:51:18

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:51
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'I'	Atifah Ayub (b) (4)	30 Nov 2020 10:24:38

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:51:18

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:51
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:24:38

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:51:18

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
User entered empty.	System	30 Nov 2020 10:24:38

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:51:18

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:51
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:24:38

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:51:18

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:51
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:24:38

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:51:18

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:51
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:24:38

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:51:18

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:51
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:24:38

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:51:18

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:51
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:24:38

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:51:18

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:51
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:24:38

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:51:18

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:51
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:24:38

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:51:18

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:51
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Atifah Ayub (b) (4)	30 Nov 2020 10:24:38

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:51:18

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:51
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Atifah Ayub (b) (4)	30 Nov 2020 10:24:38

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:51:18

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:51
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:24:38

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:51:18

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:51
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:24:38

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:51:18

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:51
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:24:38

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:51:18

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:51
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:24:38

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:51:18

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:51
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:24:38

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:51:18

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:51
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:24:38

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:51:18

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:51
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4) (b) (4)	30 Nov 2020 10:24:38

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:51:18

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:51
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:24:38

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:51:18

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'Day 12 (Day 12)'	Afifah Ayub (b) (4)	30 Nov 2020 10:24:49

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:51:18

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:53
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered '24 Nov 2020'	Atifah Ayub (b) (4)	30 Nov 2020 10:24:49

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:51:18

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:53
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'I'	Afifah Ayub (b) (4) (b) (4)	30 Nov 2020 10:24:49

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:51:18

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:53
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:24:49

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:51:18

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
User entered empty.	System	30 Nov 2020 10:24:49

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:51:18

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:53
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:24:49

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:51:18

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:53
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:24:49

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:51:18

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:53
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:24:49

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:51:18

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:53
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:24:49

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:51:18

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:53
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:24:49

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:51:18

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:53
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:24:49

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:51:18

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:53
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:24:49

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:51:18

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:53
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:24:49

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:51:18

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:53
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Atifah Ayub (b) (4)	30 Nov 2020 10:24:49

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:51:18

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:53
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4) (b) (4)	30 Nov 2020 10:24:49

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:51:18

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:53
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:24:49

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:51:18

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:53
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:24:49

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:51:18

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:53
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:24:49

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:51:18

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:53
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:24:49

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:51:18

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:53
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:24:49

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:51:18

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:53
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:24:49

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:51:18

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:46:53
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:24:49

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:51:18

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'Day 13 (Day 13)'	Afifah Ayub (b) (4)	30 Nov 2020 10:25:53

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:51:18

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:56:32
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered '25 Nov 2020'	Afifah Ayub (b) (4) (b) (4)	30 Nov 2020 10:25:53

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:51:18

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:56:32
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered '0'	Afifah Ayub (b) (4)	30 Nov 2020 10:25:53

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:51:18

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:53:31
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered '97'	Afifah Ayub (b) (4)	30 Nov 2020 10:25:53

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:51:18

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
User entered '%'	System	30 Nov 2020 10:25:53

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:51:18

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:55:51
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered '98.4' F	Afifah Ayub (b) (4)	30 Nov 2020 10:25:53

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:51:18

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:56:32
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'None (None)'	Afifah Ayub (b) (4)	30 Nov 2020 10:25:53

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:51:18

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:56:32
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'None (None)'	Afifah Ayub (b) (4)	30 Nov 2020 10:25:53

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:51:18

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:56:32
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'None (None)'	Afifah Ayub (b) (4)	30 Nov 2020 10:25:53

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:51:18

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:56:32
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'None (None)'	Afifah Ayub (b) (4)	30 Nov 2020 10:25:53

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:51:18

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:56:32
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'None (None)'	Afifah Ayub (b) (4)	30 Nov 2020 10:25:53

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:51:18

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:56:32
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'None (None)'	Afifah Ayub (b) (4)	30 Nov 2020 10:25:53

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:51:18

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:56:32
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'None (None)'	Afifah Ayub (b) (4)	30 Nov 2020 10:25:53

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:51:18

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:56:32
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'None (None)'	Afifah Ayub (b) (4)	30 Nov 2020 10:25:53

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:51:18

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:56:32
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'None (None)'	Afifah Ayub (b) (4)	30 Nov 2020 10:25:53

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:51:18

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:56:32
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'None (None)'	Afifah Ayub (b) (4)	30 Nov 2020 10:25:53

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:51:18

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:56:32
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'None (None)'	Afifah Ayub (b) (4)	30 Nov 2020 10:25:53

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:51:18

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:56:32
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'None (None)'	Afifah Ayub (b) (4)	30 Nov 2020 10:25:53

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:51:18

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:56:32
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'None (None)'	Afifah Ayub (b) (4)	30 Nov 2020 10:25:53

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:51:18

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:56:32
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'None (None)'	Afifah Ayub (b) (4)	30 Nov 2020 10:25:53

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:51:18

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:56:32
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'None (None)'	Afifah Ayub (b) (4)	30 Nov 2020 10:25:53

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:51:18

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:56:32
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'None (None)'	Afifah Ayub (b) (4)	30 Nov 2020 10:25:53

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 15:51:18

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'Day 14 (Day 14)'	Afifah Ayub (b) (4)	30 Nov 2020 10:27:21

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 15:51:18

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:57:09
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered '26 Nov 2020'	Afifah Ayub (b) (4)	30 Nov 2020 10:27:21

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 15:51:18

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:57:09
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered '0'	Afifah Ayub (b) (4)	30 Nov 2020 10:27:21

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 15:51:18

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:57:02
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered '97'	Afifah Ayub (b) (4) (b) (4)	30 Nov 2020 10:27:21

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 15:51:18

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
User entered '%'	System	30 Nov 2020 10:27:21

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 15:51:18

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:56:59
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered '97.4' F	Afifah Ayub (b) (4)	30 Nov 2020 10:27:21

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 15:51:18

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:57:09
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'None (None)'	Afifah Ayub (b) (4)	30 Nov 2020 10:27:21

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 15:51:18

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:57:09
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'None (None)'	Afifah Ayub (b) (4)	30 Nov 2020 10:27:21

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 15:51:18

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:57:09
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'None (None)'	Afifah Ayub (b) (4)	30 Nov 2020 10:27:21

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 15:51:18

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:57:09
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'None (None)'	Afifah Ayub (b) (4)	30 Nov 2020 10:27:21

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 15:51:18

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:57:09
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'None (None)'	Afifah Ayub (b) (4)	30 Nov 2020 10:27:21

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 15:51:18

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:57:09
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'None (None)'	Afifah Ayub (b) (4)	30 Nov 2020 10:27:21

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 15:51:18

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:57:09
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'None (None)'	Afifah Ayub (b) (4)	30 Nov 2020 10:27:21

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 15:51:18

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:57:09
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'None (None)'	Afifah Ayub (b) (4)	30 Nov 2020 10:27:21

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 15:51:18

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:57:09
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'None (None)'	Afifah Ayub (b) (4)	30 Nov 2020 10:27:21

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 15:51:18

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:57:09
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'None (None)'	Afifah Ayub (b) (4)	30 Nov 2020 10:27:21

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 15:51:18

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:57:09
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'None (None)'	Afifah Ayub (b) (4)	30 Nov 2020 10:27:21

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 15:51:18

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:57:09
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'None (None)'	Afifah Ayub (b) (4)	30 Nov 2020 10:27:21

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 15:51:18

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:57:09
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'None (None)'	Afifah Ayub (b) (4)	30 Nov 2020 10:27:21

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 15:51:18

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:57:09
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'None (None)'	Afifah Ayub (b) (4)	30 Nov 2020 10:27:21

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 15:51:18

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:57:09
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'None (None)'	Afifah Ayub (b) (4)	30 Nov 2020 10:27:21

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 15:51:18

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:57:09
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'None (None)'	Afifah Ayub (b) (4)	30 Nov 2020 10:27:21

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 15:51:18

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'Day 15 (Day 15)'	Afifah Ayub (b) (4)	30 Nov 2020 10:28:32

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 15:51:18

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:57:50
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered '27 Nov 2020'	Afifah Ayub (b) (4)	30 Nov 2020 10:28:32

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 15:51:18

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:57:50
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered '0'	Afifah Ayub (b) (4)	30 Nov 2020 10:28:32

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 15:51:18

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:57:50
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered '97'	Afifah Ayub (b) (4)	30 Nov 2020 10:28:32

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 15:51:18

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
User entered '%'	System	30 Nov 2020 10:28:32

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 15:51:18

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:57:28
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered '97.6' F	Afifah Ayub (b) (4) (b) (4)	30 Nov 2020 10:28:32

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 15:51:18

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:57:50
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'None (None)'	Afifah Ayub (b) (4)	30 Nov 2020 10:28:32

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 15:51:18

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:57:50
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'None (None)'	Afifah Ayub (b) (4)	30 Nov 2020 10:28:32

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 15:51:18

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:57:50
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'None (None)'	Afifah Ayub (b) (4)	30 Nov 2020 10:28:32

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 15:51:18

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:57:50
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'None (None)'	Afifah Ayub (b) (4)	30 Nov 2020 10:28:32

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 15:51:18

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:57:50
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'None (None)'	Afifah Ayub (b) (4)	30 Nov 2020 10:28:32

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 15:51:18

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:57:50
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'None (None)'	Afifah Ayub (b) (4)	30 Nov 2020 10:28:32

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 15:51:18

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:57:50
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'None (None)'	Afifah Ayub (b) (4)	30 Nov 2020 10:28:32

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 15:51:18

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:57:50
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'None (None)'	Afifah Ayub (b) (4)	30 Nov 2020 10:28:32

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 15:51:18

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:57:50
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'None (None)'	Afifah Ayub (b) (4)	30 Nov 2020 10:28:32

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 15:51:18

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:57:50
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'None (None)'	Afifah Ayub (b) (4)	30 Nov 2020 10:28:32

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 15:51:18

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:57:50
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'None (None)'	Afifah Ayub (b) (4)	30 Nov 2020 10:28:32

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 15:51:18

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:57:50
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'None (None)'	Afifah Ayub (b) (4)	30 Nov 2020 10:28:32

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 15:51:18

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:57:50
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'None (None)'	Afifah Ayub (b) (4)	30 Nov 2020 10:28:32

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 15:51:18

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:57:50
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'None (None)'	Afifah Ayub (b) (4)	30 Nov 2020 10:28:32

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 15:51:18

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:57:50
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'None (None)'	Afifah Ayub (b) (4)	30 Nov 2020 10:28:32

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 15:51:18

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:57:50
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'None (None)'	Afifah Ayub (b) (4)	30 Nov 2020 10:28:32

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 15:51:18

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'Day 16 (Day 16)'	Afifah Ayub (b) (4)	30 Nov 2020 10:29:52

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 15:51:18

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:58:35
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered '28 Nov 2020'	Afifah Ayub (b) (4) (b) (4)	30 Nov 2020 10:29:52

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 15:51:18

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:58:35
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered '0'	Afifah Ayub (b) (4)	30 Nov 2020 10:29:52

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 15:51:18

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:58:23
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered '100'	Afifah Ayub (b) (4) (b) (4)	30 Nov 2020 10:29:52

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 15:51:18

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
User entered '%'	System	30 Nov 2020 10:29:52

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 15:51:18

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:58:21
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered '99.5' F	Afifah Ayub (b) (4)	30 Nov 2020 10:29:52

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 15:51:18

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:58:35
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'None (None)'	Afifah Ayub (b) (4)	30 Nov 2020 10:29:52

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 15:51:18

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:58:35
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'None (None)'	Afifah Ayub (b) (4)	30 Nov 2020 10:29:52

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 15:51:18

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:58:35
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'None (None)'	Afifah Ayub (b) (4)	30 Nov 2020 10:29:52

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 15:51:18

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:58:35
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'None (None)'	Afifah Ayub (b) (4)	30 Nov 2020 10:29:52

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 15:51:18

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:58:35
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'None (None)'	Afifah Ayub (b) (4)	30 Nov 2020 10:29:52

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 15:51:18

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:58:35
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'None (None)'	Afifah Ayub (b) (4)	30 Nov 2020 10:29:52

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 15:51:18

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:58:35
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'None (None)'	Afifah Ayub (b) (4)	30 Nov 2020 10:29:52

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 15:51:18

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:58:35
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'None (None)'	Afifah Ayub (b) (4)	30 Nov 2020 10:29:52

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 15:51:18

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:58:35
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'None (None)'	Afifah Ayub (b) (4)	30 Nov 2020 10:29:52

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 15:51:18

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:58:35
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'None (None)'	Afifah Ayub (b) (4)	30 Nov 2020 10:29:52

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 15:51:18

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:58:35
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'None (None)'	Afifah Ayub (b) (4)	30 Nov 2020 10:29:52

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 15:51:18

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:58:35
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'None (None)'	Afifah Ayub (b) (4)	30 Nov 2020 10:29:52

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 15:51:18

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:58:35
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'None (None)'	Afifah Ayub (b) (4)	30 Nov 2020 10:29:52

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 15:51:18

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:58:35
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'None (None)'	Afifah Ayub (b) (4)	30 Nov 2020 10:29:52

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 15:51:18

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:58:35
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'None (None)'	Afifah Ayub (b) (4)	30 Nov 2020 10:29:52

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 15:51:18

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:58:35
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'None (None)'	Afifah Ayub (b) (4)	30 Nov 2020 10:29:52

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 15:51:18

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'Day 17 (Day 17)'	Afifah Ayub (b) (4)	30 Nov 2020 10:30:56

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 15:51:18

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:59:13
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered '29 Nov 2020'	Atifah Ayub (b) (4)	30 Nov 2020 10:30:56

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 15:51:18

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:59:13
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered '0'	Afifah Ayub (b) (4)	30 Nov 2020 10:30:56

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 15:51:18

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:59:01
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered '97'	Afifah Ayub (b) (4)	30 Nov 2020 10:30:56

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 15:51:18

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
User entered '%'	System	30 Nov 2020 10:30:56

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 15:51:18

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:58:56
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered '98.5' F	Afifah Ayub (b) (4)	30 Nov 2020 10:30:56

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 15:51:18

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:59:13
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'None (None)'	Afifah Ayub (b) (4)	30 Nov 2020 10:30:56

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 15:51:18

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:59:13
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'None (None)'	Afifah Ayub (b) (4)	30 Nov 2020 10:30:56

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 15:51:18

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:59:13
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'None (None)'	Afifah Ayub (b) (4)	30 Nov 2020 10:30:56

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 15:51:18

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:59:13
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'None (None)'	Afifah Ayub (b) (4)	30 Nov 2020 10:30:56

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 15:51:18

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:59:13
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'None (None)'	Afifah Ayub (b) (4)	30 Nov 2020 10:30:56

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 15:51:18

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:59:13
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'None (None)'	Afifah Ayub (b) (4)	30 Nov 2020 10:30:56

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 15:51:18

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:59:13
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'None (None)'	Afifah Ayub (b) (4)	30 Nov 2020 10:30:56

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 15:51:18

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:59:13
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'None (None)'	Afifah Ayub (b) (4)	30 Nov 2020 10:30:56

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 15:51:18

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:59:13
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'None (None)'	Afifah Ayub (b) (4)	30 Nov 2020 10:30:56

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 15:51:18

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:59:13
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'None (None)'	Afifah Ayub (b) (4)	30 Nov 2020 10:30:56

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 15:51:18

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:59:13
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'None (None)'	Afifah Ayub (b) (4)	30 Nov 2020 10:30:56

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 15:51:18

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:59:13
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'None (None)'	Afifah Ayub (b) (4)	30 Nov 2020 10:30:56

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 15:51:18

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:59:13
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'None (None)'	Afifah Ayub (b) (4)	30 Nov 2020 10:30:56

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 15:51:18

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:59:13
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'None (None)'	Afifah Ayub (b) (4)	30 Nov 2020 10:30:56

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 15:51:18

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:59:13
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'None (None)'	Afifah Ayub (b) (4)	30 Nov 2020 10:30:56

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 15:51:18

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:59:13
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'None (None)'	Afifah Ayub (b) (4)	30 Nov 2020 10:30:56

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 15:51:18

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'Day 18 (Day 18)'	Afifah Ayub (b) (4)	01 Dec 2020 15:12:59

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 15:51:18

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 06:00:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered '30 Nov 2020'	Afifah Ayub (b) (4)	01 Dec 2020 15:12:59

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 15:51:18

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 06:00:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered '0'	Afifah Ayub (b) (4) (b) (4)	01 Dec 2020 15:12:59

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 15:51:18

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 06:00:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered '97'	Afifah Ayub (b) (4) (b) (4)	01 Dec 2020 15:12:59

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 15:51:18

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
User entered '%'	System	01 Dec 2020 15:12:59

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 15:51:18

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:59:45
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered '97.9' F	Afifah Ayub (b) (4) (b) (4)	01 Dec 2020 15:12:59

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 15:51:18

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 06:00:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'None (None)'	Afifah Ayub (b) (4)	01 Dec 2020 15:12:59

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 15:51:18

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 06:00:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'None (None)'	Afifah Ayub (b) (4)	01 Dec 2020 15:12:59

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 15:51:18

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 06:00:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'None (None)'	Afifah Ayub (b) (4)	01 Dec 2020 15:12:59

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 15:51:18

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 06:00:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'None (None)'	Afifah Ayub (b) (4)	01 Dec 2020 15:12:59

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 15:51:18

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 06:00:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'None (None)'	Afifah Ayub (b) (4)	01 Dec 2020 15:12:59

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 15:51:18

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 06:00:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'None (None)'	Afifah Ayub (b) (4)	01 Dec 2020 15:12:59

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 15:51:18

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 06:00:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'None (None)'	Afifah Ayub (b) (4)	01 Dec 2020 15:12:59

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 15:51:18

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 06:00:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'None (None)'	Afifah Ayub (b) (4)	01 Dec 2020 15:12:59

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 15:51:18

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 06:00:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'None (None)'	Afifah Ayub (b) (4)	01 Dec 2020 15:12:59

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 15:51:18

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 06:00:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'None (None)'	Afifah Ayub (b) (4)	01 Dec 2020 15:12:59

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 15:51:18

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 06:00:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'None (None)'	Afifah Ayub (b) (4)	01 Dec 2020 15:12:59

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 15:51:18

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 06:00:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'None (None)'	Afifah Ayub (b) (4)	01 Dec 2020 15:12:59

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 15:51:18

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 06:00:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'None (None)'	Afifah Ayub (b) (4)	01 Dec 2020 15:12:59

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 15:51:18

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 06:00:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'None (None)'	Afifah Ayub (b) (4)	01 Dec 2020 15:12:59

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 15:51:18

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 06:00:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'None (None)'	Afifah Ayub (b) (4)	01 Dec 2020 15:12:59

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 15:51:18

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 06:00:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'None (None)'	Afifah Ayub (b) (4)	01 Dec 2020 15:12:59

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 15:51:18

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'Day 19 (Day 19)'	Afifah Ayub (b) (4)	04 Dec 2020 15:09:17

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 15:51:18

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 06:01:35
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered '01 Dec 2020'	Afifah Ayub (b) (4)	04 Dec 2020 15:09:17

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 15:51:18

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 06:01:35
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered '0'	Afifah Ayub (b) (4)	04 Dec 2020 15:09:17

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 15:51:18

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 06:01:19
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered '96'	Afifah Ayub (b) (4) (b) (4)	04 Dec 2020 15:09:17

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 15:51:18

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
User entered '%'	System	04 Dec 2020 15:09:17

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 15:51:18

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 06:01:21
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered '98.0' F	Afifah Ayub (b) (4) (b) (4)	04 Dec 2020 15:09:17

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 15:51:18

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 06:01:35
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'None (None)'	Afifah Ayub (b) (4)	04 Dec 2020 15:09:17

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 15:51:18

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 06:01:35
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'None (None)'	Afifah Ayub (b) (4)	04 Dec 2020 15:09:17

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 15:51:18

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 06:01:35
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'None (None)'	Afifah Ayub (b) (4)	04 Dec 2020 15:09:17

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 15:51:18

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 06:01:35
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'None (None)'	Afifah Ayub (b) (4)	04 Dec 2020 15:09:17

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 15:51:18

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 06:01:35
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'None (None)'	Afifah Ayub (b) (4)	04 Dec 2020 15:09:17

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 15:51:18

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 06:01:35
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'None (None)'	Afifah Ayub (b) (4)	04 Dec 2020 15:09:17

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 15:51:18

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 06:01:35
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'None (None)'	Afifah Ayub (b) (4)	04 Dec 2020 15:09:17

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 15:51:18

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 06:01:35
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'None (None)'	Afifah Ayub (b) (4)	04 Dec 2020 15:09:17

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 15:51:18

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 06:01:35
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'None (None)'	Afifah Ayub (b) (4)	04 Dec 2020 15:09:17

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 15:51:18

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 06:01:35
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'None (None)'	Afifah Ayub (b) (4)	04 Dec 2020 15:09:17

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 15:51:18

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 06:01:35
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'None (None)'	Afifah Ayub (b) (4)	04 Dec 2020 15:09:17

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 15:51:18

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 06:01:35
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'None (None)'	Afifah Ayub (b) (4)	04 Dec 2020 15:09:17

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 15:51:18

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 06:01:35
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'None (None)'	Afifah Ayub (b) (4)	04 Dec 2020 15:09:17

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 15:51:18

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 06:01:35
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'None (None)'	Afifah Ayub (b) (4)	04 Dec 2020 15:09:17

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 15:51:18

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 06:01:35
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'None (None)'	Afifah Ayub (b) (4)	04 Dec 2020 15:09:17

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 15:51:18

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 06:01:35
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'None (None)'	Afifah Ayub (b) (4)	04 Dec 2020 15:09:17

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 15:51:18

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'Day 20 (Day 20)'	Afifah Ayub (b) (4)	04 Dec 2020 15:09:58

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 15:51:18

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 06:04:49
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered '02 Dec 2020'	Afifah Ayub (b) (4)	04 Dec 2020 15:09:58

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 15:51:18

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 06:04:49
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered '0'	Afifah Ayub (b) (4) (b) (4)	04 Dec 2020 15:09:58

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 15:51:18

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 06:01:50
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered '99'	Afifah Ayub (b) (4)	04 Dec 2020 15:09:58

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 15:51:18

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
User entered '%'	System	04 Dec 2020 15:09:58

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 15:51:18

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 06:01:52
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered '97.9' F	Afifah Ayub (b) (4) (b) (4)	04 Dec 2020 15:09:58

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 15:51:18

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 06:04:49
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'None (None)'	Afifah Ayub (b) (4)	04 Dec 2020 15:09:58

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 15:51:18

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 06:04:49
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'None (None)'	Afifah Ayub (b) (4)	04 Dec 2020 15:09:58

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 15:51:18

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 06:04:49
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'None (None)'	Afifah Ayub (b) (4)	04 Dec 2020 15:09:58

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 15:51:18

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 06:04:49
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'None (None)'	Afifah Ayub (b) (4)	04 Dec 2020 15:09:58

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 15:51:18

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 06:04:49
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'None (None)'	Afifah Ayub (b) (4)	04 Dec 2020 15:09:58

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 15:51:18

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 06:04:49
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'None (None)'	Afifah Ayub (b) (4)	04 Dec 2020 15:09:58

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 15:51:18

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 06:04:49
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'None (None)'	Afifah Ayub (b) (4)	04 Dec 2020 15:09:58

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 15:51:18

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 06:04:49
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'None (None)'	Afifah Ayub (b) (4)	04 Dec 2020 15:09:58

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 15:51:18

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 06:04:49
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'None (None)'	Afifah Ayub (b) (4)	04 Dec 2020 15:09:58

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 15:51:18

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 06:04:49
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'None (None)'	Afifah Ayub (b) (4)	04 Dec 2020 15:09:58

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 15:51:18

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 06:04:49
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'None (None)'	Afifah Ayub (b) (4)	04 Dec 2020 15:09:58

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 15:51:18

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 06:04:49
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'None (None)'	Afifah Ayub (b) (4)	04 Dec 2020 15:09:58

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 15:51:18

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 06:04:49
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'None (None)'	Afifah Ayub (b) (4)	04 Dec 2020 15:09:58

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 15:51:18

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 06:04:49
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'None (None)'	Afifah Ayub (b) (4)	04 Dec 2020 15:09:58

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 15:51:18

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 06:04:49
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'None (None)'	Afifah Ayub (b) (4)	04 Dec 2020 15:09:58

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 15:51:18

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 06:04:49
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'None (None)'	Afifah Ayub (b) (4)	04 Dec 2020 15:09:58

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 15:51:18

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'Day 21 (Day 21)'	Afifah Ayub (b) (4)	04 Dec 2020 15:10:45

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 15:51:18

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 06:05:39
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered '03 Dec 2020'	Afifah Ayub (b) (4) (b) (4)	04 Dec 2020 15:10:45

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 15:51:18

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 06:05:39
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered '0'	Afifah Ayub (b) (4)	04 Dec 2020 15:10:45

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 15:51:18

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 06:05:18
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered '98'	Afifah Ayub (b) (4)	04 Dec 2020 15:10:45

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 15:51:18

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
User entered '%'	System	04 Dec 2020 15:10:45

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 15:51:18

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 06:05:16
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered '98.7' F	Afifah Ayub (b) (4) (b) (4)	04 Dec 2020 15:10:45

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 15:51:18

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 06:05:39
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'None (None)'	Afifah Ayub (b) (4)	04 Dec 2020 15:10:45

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 15:51:18

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 06:05:39
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'None (None)'	Afifah Ayub (b) (4)	04 Dec 2020 15:10:45

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 15:51:18

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 06:05:39
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'None (None)'	Afifah Ayub (b) (4)	04 Dec 2020 15:10:45

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 15:51:18

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 06:05:39
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'None (None)'	Afifah Ayub (b) (4)	04 Dec 2020 15:10:45

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 15:51:18

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 06:05:39
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'None (None)'	Afifah Ayub (b) (4)	04 Dec 2020 15:10:45

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 15:51:18

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 06:05:39
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'None (None)'	Afifah Ayub (b) (4)	04 Dec 2020 15:10:45

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 15:51:18

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 06:05:39
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'None (None)'	Afifah Ayub (b) (4)	04 Dec 2020 15:10:45

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 15:51:18

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 06:05:39
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'None (None)'	Afifah Ayub (b) (4)	04 Dec 2020 15:10:45

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 15:51:18

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 06:05:39
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'None (None)'	Afifah Ayub (b) (4)	04 Dec 2020 15:10:45

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 15:51:18

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 06:05:39
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'None (None)'	Afifah Ayub (b) (4)	04 Dec 2020 15:10:45

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 15:51:18

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 06:05:39
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'None (None)'	Afifah Ayub (b) (4)	04 Dec 2020 15:10:45

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 15:51:18

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 06:05:39
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'None (None)'	Afifah Ayub (b) (4)	04 Dec 2020 15:10:45

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 15:51:18

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 06:05:39
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'None (None)'	Afifah Ayub (b) (4)	04 Dec 2020 15:10:45

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 15:51:18

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 06:05:39
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'None (None)'	Afifah Ayub (b) (4)	04 Dec 2020 15:10:45

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 15:51:18

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 06:05:39
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'None (None)'	Afifah Ayub (b) (4)	04 Dec 2020 15:10:45

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 15:51:18

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 06:05:39
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'None (None)'	Afifah Ayub (b) (4)	04 Dec 2020 15:10:45

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:51:18

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:35
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:47:37
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered '25 Nov 2020'	Afifah Ayub (b) (4)	30 Nov 2020 10:31:23

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:51:18

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:35
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:47:37
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	30 Nov 2020 10:31:23

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:51:18

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:35
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:47:37
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	16 Dec 2020 16:16:30
User entered 'No (N)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	07 Dec 2020 14:40:20
Query 'Data is required. Please complete.' answered with 'will add later' (Site from System).	(b) (4)	30 Nov 2020 10:31:30
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Nov 2020 10:31:23
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:31:23

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: COVID Diagnostic Test

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[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:35
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:47:37
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered '25 Nov 2020'	Afifah Ayub (b) (4)	30 Nov 2020 10:31:23

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Folder: Covid-19 Assessment 25 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:51:18

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:35
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:47:37
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'Nasopharyngeal Swab (Nasopharyngeal Afifah Ayub Swab)'	(b) (4)	30 Nov 2020 10:31:23

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Folder: Covid-19 Assessment 25 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:51:18

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:35
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:47:37
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:31:23

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:51:18

[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)	29 Apr 2021 05:35:35
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:47:37
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'No (N)'	Afifah Ayub (b) (4)	30 Nov 2020 10:31:23

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Folder: Covid-19 Assessment 25 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:51:18

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:35
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:47:37
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:31:23

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:51:18

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:35
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:47:37
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:31:23

US3212394

Folder: Covid-19 Assessment 25 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:51:18

COVID-19 Positive (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:35
User entered '0'	System	07 Dec 2020 14:40:20

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 15:51:18

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:41
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:47:44
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'No (N)'	Afifah Ayub (b) (4)	30 Nov 2020 10:21:01

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Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 15:51:18

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	Afifah Ayub (b) (4) (b) (4)	30 Nov 2020 10:33:55

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Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 15:51:18

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 06:07:27
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	30 Nov 2020 10:33:55

US3212394

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 15:51:18

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 06:07:27
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered '27 Nov 2020'	Afifah Ayub (b) (4)	30 Nov 2020 10:33:55

US3212394

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 15:51:18

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	Afifah Ayub (b) (4) (b) (4)	30 Nov 2020 10:33:55

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Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 15:51:18

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 06:07:47
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	30 Nov 2020 10:33:55

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Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 15:51:18

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 06:07:47
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered '29 Nov 2020'	Afifah Ayub (b) (4)	30 Nov 2020 10:33:55

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Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 15:51:18

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	Afifah Ayub (b) (4) (b) (4)	30 Nov 2020 10:33:55

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Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 15:51:18

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 06:08:11
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'Yes (Y)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	04 Dec 2020 15:11:29
User entered 'No (N)'	Afifah Ayub (b) (4)	30 Nov 2020 10:33:55

US3212394

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 15:51:18

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 06:08:11
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered '01 Dec 2020' reason for change: Data Entry Error	Afifah Ayub (b) (4)	04 Dec 2020 15:11:29
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:33:55

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Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 15:51:18

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	Afifah Ayub (b) (4) (b) (4)	30 Nov 2020 10:33:55

US3212394

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 15:51:18

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 06:08:37
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'Yes (Y)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	04 Dec 2020 15:11:29
User entered 'No (N)'	Afifah Ayub (b) (4)	30 Nov 2020 10:33:55

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Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 15:51:18

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 06:08:37
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered '03 Dec 2020' reason for change: Data Entry Error	Afifah Ayub (b) (4)	04 Dec 2020 15:11:29
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:33:55

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Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 15:51:18

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	Afifah Ayub (b) (4) (b) (4)	30 Nov 2020 10:33:55

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Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 15:51:18

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 06:08:38
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	07 Dec 2020 14:41:01
User entered 'No (N)'	Afifah Ayub (b) (4)	30 Nov 2020 10:33:55

US3212394

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 15:51:18

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 06:08:38
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:33:55

US3212394

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 15:51:18

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	Afifah Ayub (b) (4) (b) (4)	30 Nov 2020 10:33:55

US3212394

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 15:51:18

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 06:08:40
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	07 Dec 2020 14:41:01
User entered 'No (N)'	Afifah Ayub (b) (4)	30 Nov 2020 10:33:55

US3212394

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 15:51:18

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 06:08:40
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:33:55

US3212394

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 15:51:18

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Afifah Ayub (b) (4) (b) (4)	30 Nov 2020 10:33:55

US3212394

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 15:51:18

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 06:08:45
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	07 Dec 2020 14:41:01
User entered 'No (N)'	Afifah Ayub (b) (4)	30 Nov 2020 10:33:55

US3212394

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 15:51:18

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 06:08:45
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:33:55

US3212394

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:51:18

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:14:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:47:52
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'Yes (Y)'	Afifah Ayub (b) (4) (b) (4)	30 Nov 2020 10:32:14

US3212394

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:51:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:14:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:47:52
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered '25 Nov 2020'	Atifah Ayub (b) (4)	30 Nov 2020 10:32:14

US3212394

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:51:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:14:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:47:52
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'Clinic (Clinic)'	Afifah Ayub (b) (4)	30 Nov 2020 10:32:14

US3212394

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:51:18

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:14:57
User entered 'SICKD1'	System	30 Nov 2020 10:32:14

US3212394

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:51:18

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:14:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:48:16
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	30 Nov 2020 10:33:05

US3212394

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:51:18

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:14:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:48:16
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered '25 Nov 2020'	Afifah Ayub (b) (4)	30 Nov 2020 10:33:05

US3212394

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:51:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:14:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:47:59
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered '13:05'	Afifah Ayub (b) (4) (b) (4)	30 Nov 2020 10:33:05

US3212394

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:51:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:14:57
User entered '25 Nov 2020 13:05'	System	30 Nov 2020 10:33:05

US3212394

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:51:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:14:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:48:16
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered missing code ND - Not Done.	Afifah Ayub (b) (4)	30 Nov 2020 10:33:05
DataPoint set to visible.	(b) (4) System	30 Nov 2020 10:32:14

US3212394

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:51:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:14:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:48:16
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered missing code ND - Not Done.	Afifah Ayub (b) (4)	30 Nov 2020 10:33:05
DataPoint set to visible.	(b) (4) System	30 Nov 2020 10:32:14

US3212394

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:51:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:14:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:48:03
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered '98.4' F	Afifah Ayub (b) (4)	30 Nov 2020 10:33:05

US3212394

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:51:18

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:14:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:48:16
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'Oral (Oral)'	Afifah Ayub (b) (4)	30 Nov 2020 10:33:05

US3212394

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:51:18

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:14:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:48:16
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	30 Nov 2020 10:33:05

US3212394

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:51:18

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:14:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:48:08
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered '101'	Afifah Ayub (b) (4) (b) (4)	30 Nov 2020 10:33:05

US3212394

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:51:18

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:14:57
User entered 'bpm'	System	30 Nov 2020 10:33:05

US3212394

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:51:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:14:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:48:11
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered '18'	Afifah Ayub (b) (4)	30 Nov 2020 10:33:05

US3212394

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:51:18

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:14:57
User entered 'breaths/min'	System	30 Nov 2020 10:33:05

US3212394

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:51:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:14:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:48:16
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered '118'	Atifah Ayub (b) (4)	30 Nov 2020 10:33:05

US3212394

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:51:18

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:14:57
User entered 'mmHg'	System	30 Nov 2020 10:33:05

US3212394

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:51:18

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:14:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:48:16
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered '68'	Atifah Ayub (b) (4)	30 Nov 2020 10:33:05

US3212394

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:51:18

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:14:57
User entered 'mmHg'	System	30 Nov 2020 10:33:05

US3212394

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:51:18

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:14:57

US3212394

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:51:18

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:14:57

US3212394

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:51:18

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:14:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:48:24
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'Yes (Y)'	Atifah Ayub (b) (4)	30 Nov 2020 10:33:13

US3212394

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:51:18

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:14:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:48:24
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered '25 Nov 2020'	Afifah Ayub (b) (4)	30 Nov 2020 10:33:13

US3212394

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 15:51:18

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:14:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:48:56
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	30 Nov 2020 10:33:21

US3212394

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 15:51:18

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:14:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:48:56
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User closed query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 25 NOV 2020 is recorded under illness Visit Day 1 visit in EDC, however the same SARS-CoV-2 serum sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	08 Dec 2020 08:08:14
Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 25 NOV 2020 is recorded under illness Visit Day 1 visit in EDC, however the same SARS-CoV-2 serum sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' answered with 'Accession: 1F60IHK' (Site from DM).	Reagan Reed (b) (4) (b) (4)	07 Dec 2020 14:27:49
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 25 NOV 2020 is recorded under illness Visit Day 1 visit in EDC, however the same SARS-CoV-2 serum sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	07 Dec 2020 06:41:57
User entered '25 Nov 2020'	Afifah Ayub (b) (4) (b) (4)	30 Nov 2020 10:33:21

US3212394

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:51:18

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:57:55
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'No (N)'	Afifah Ayub (b) (4)	07 Dec 2020 14:40:33

US3212394

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:51:18

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:57:55
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	07 Dec 2020 14:40:33

US3212394

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:51:18

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:57:55
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	07 Dec 2020 14:40:33

US3212394

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:51:18

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD28'	System	07 Dec 2020 14:40:33

US3212394

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:51:18

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:49:52
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'No (N)'	Afifah Ayub (b) (4)	07 Dec 2020 14:40:38

US3212394

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:51:18

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:49:52
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	07 Dec 2020 14:40:38

US3212394

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:51:18

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:49:52
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	07 Dec 2020 14:40:38

US3212394

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:51:18

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Dec 2020 14:40:38

US3212394

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:51:18

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:49:52
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	07 Dec 2020 14:40:38

US3212394

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:51:18

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:49:52
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	07 Dec 2020 14:40:38

US3212394

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:51:18

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:49:52
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	07 Dec 2020 14:40:38

US3212394

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:51:18

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:49:52
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	07 Dec 2020 14:40:38

US3212394

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:51:18

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Dec 2020 14:40:38

US3212394

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:51:18

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:49:52
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	07 Dec 2020 14:40:38

US3212394

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:51:18

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Dec 2020 14:40:38

US3212394

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:51:18

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:49:52
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	07 Dec 2020 14:40:38

US3212394

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:51:18

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Dec 2020 14:40:38

US3212394

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:51:18

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:49:52
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	07 Dec 2020 14:40:38

US3212394

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:51:18

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Dec 2020 14:40:38

US3212394

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:51:18

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:49:55
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'No (N)'	Afifah Ayub (b) (4)	07 Dec 2020 14:40:43

US3212394

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:51:18

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:49:55
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	07 Dec 2020 14:40:43

US3212394

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 15:51:18

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:49:59
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'NA (COVID-19 Negative) (NA)'	Afifah Ayub (b) (4)	07 Dec 2020 14:40:48

US3212394

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 15:51:18

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:49:59
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Afifah Ayub (b) (4)	07 Dec 2020 14:40:48

US3212394

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:51:18

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:26:15
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:43:42
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'Yes (Y)'	Heather Leary (b) (4)	08 Jan 2021 21:36:23

US3212394

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:51:18

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:26:15
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:43:42
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered '8 Jan 2021'	Heather Leary (b) (4)	08 Jan 2021 21:36:23

US3212394

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:51:18

[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 14:26:15
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:43:42
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'Clinic (Clinic)'	Heather Leary (b) (4)	08 Jan 2021 21:36:23

US3212394

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:51:18

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:26:15
User entered 'UNBLND_DECIDE'	System	08 Jan 2021 21:36:23

US3212394

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:51:18

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:26:15
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:43:58
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered '8 Jan 2021'	Heather Leary (b) (4)	08 Jan 2021 21:36:36

US3212394

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:51:18

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:26:15
User signature succeeded.	Insiya Valika (b) (4)	22 Apr 2021 19:38:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:34:18
User entered '0'	Heather Leary (b) (4)	22 Apr 2021 14:38:57
Amendment Manager inserted this DataPoint.	(b) (4) System	06 Mar 2021 08:55:10

US3212394

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:51:18

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:26:15
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:43:58
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'Yes (Y)'	Heather Leary (b) (4)	08 Jan 2021 21:36:36

US3212394

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:51:18

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:26:15
User closed query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM). User signature succeeded.	(b) (4), (b) (6)	23 Apr 2021 20:00:19
DataPoint Verified.	Insiya Valika (b) (4) (b) (4)	22 Apr 2021 19:38:58
Query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' answered with 'done' (Site from DM).	(b) (4), (b) (6)	22 Apr 2021 18:34:20
User entered 'Amendment 6 or later (Amendment 6 or later)'	Heather Leary (b) (4) (b) (4)	22 Apr 2021 14:39:11
User opened query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).	Heather Leary (b) (4) (b) (4)	22 Apr 2021 14:38:57
Amendment Manager inserted this DataPoint.	(b) (4), (b) (6)	22 Apr 2021 06:54:13
	System	06 Mar 2021 08:55:10

US3212394

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:51:18

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:26:15
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:43:58
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered '8 Jan 2021'	Heather Leary (b) (4)	08 Jan 2021 21:36:36

US3212394

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:51:18

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:26:15
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:43:58
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'mRNA-1273 (mRNA-1273)'	Heather Leary (b) (4)	08 Jan 2021 21:36:36

US3212394

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:51:18

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:26:15
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:43:58
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	System	20 Jan 2021 04:38:36
User entered 'mRNA-1273 (mRNA-1273)'	Heather Leary (b) (4)	08 Jan 2021 21:36:36

US3212394

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:51:18

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:26:15
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:43:58
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	System	20 Jan 2021 04:38:36
User entered 'mRNA-1273 (mRNA-1273)'	Heather Leary (b) (4)	08 Jan 2021 21:36:36

US3212394

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:51:18

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:26:15
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:43:58
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'No (N)'	Heather Leary (b) (4)	08 Jan 2021 21:36:36

US3212394

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:51:18

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:26:15
User entered empty.	System	08 Jan 2021 21:36:36

US3212394

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:51:18

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:26:15
User entered empty.	System	08 Jan 2021 21:36:36

US3212394

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:51:18

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:26:15
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:44:09
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'Yes (Y)'	Heather Leary (b) (4)	08 Jan 2021 21:36:48

US3212394

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:51:18

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:26:15
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:44:09
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered '8 Jan 2021'	Heather Leary (b) (4)	08 Jan 2021 21:36:48

US3212394

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:51:18

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:26:15
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:44:09
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered '14:42'	Heather Leary (b) (4)	08 Jan 2021 21:36:48

US3212394

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:51:18

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:26:15
User entered '8 Jan 2021 14:42'	System	08 Jan 2021 21:36:48

US3212394

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:51:18

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:26:15
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:44:22
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'Yes (Y)'	Heather Leary (b) (4)	08 Jan 2021 21:36:58

US3212394

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:51:18

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:26:15
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:44:22
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered '8 Jan 2021'	Heather Leary (b) (4)	08 Jan 2021 21:36:58

US3212394

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:51:18

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:26:15
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:44:22
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered '14:38'	Heather Leary (b) (4)	08 Jan 2021 21:36:58

US3212394

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:51:18

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:26:15
User entered '8 Jan 2021 14:38'	System	08 Jan 2021 21:36:58

US3212394

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 15:51:18

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:28:43
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User closed query 'Per DM CLR: As per Safety Follow-up Diary entry in Day 64, Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	26 Mar 2021 14:23:05
User closed query 'Per DM CLR: As per Safety Follow-up Diary entry in Day 75, Experienced any new COVID-19 symptoms since last questionnaire or study contact? = Yes, Muscles Aches and Headache = checked. however, please note that there is no corresponding AE for Diarrhea within the timeframe. Please reconcile and update to record the AE as applicable, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	26 Mar 2021 14:23:03
Query 'Per DM CLR: As per Safety Follow-up Diary entry in Day 64, Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' answered with 'all data is entered for this subject' (Site from DM).	Reagan Reed (b) (4)	22 Mar 2021 14:29:29

US3212394

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 15:51:18

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: As per Safety Follow-up Diary entry in Day 75, Experienced any new COVID-19 symptoms since last questionnaire or study contact? = Yes, Muscles Aches and Headache = checked. however, please note that there is no corresponding AE for Diarrhea within the timeframe. Please reconcile and update to record the AE as applicable, otherwise provide clarification. ' answered with 'all data is entered for this subject' (Site from DM). User opened query 'Per DM CLR: As per Safety Follow-up Diary entry in Day 64, Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' (Site from DM).	Reagan Reed (b) (4) (b) (4)	22 Mar 2021 14:29:26
User opened query 'Per DM CLR: As per Safety Follow-up Diary entry in Day 75, Experienced any new COVID-19 symptoms since last questionnaire or study contact? = Yes, Muscles Aches and Headache = checked. however, please note that there is no corresponding AE for Diarrhea within the timeframe. Please reconcile and update to record the AE as applicable, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	21 Mar 2021 16:04:32
User opened query 'Per DM CLR: As per Safety Follow-up Diary entry in Day 75, Experienced any new COVID-19 symptoms since last questionnaire or study contact? = Yes, Muscles Aches and Headache = checked. however, please note that there is no corresponding AE for Diarrhea within the timeframe. Please reconcile and update to record the AE as applicable, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	21 Mar 2021 16:00:22
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 15:34:01
User entered 'Yes (Y)' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	05 Oct 2020 14:13:45
User entered 'No (N)'	Afifah Ayub (b) (4) (b) (4)	14 Sep 2020 00:18:57

US3212394

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:51:18

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:57

US3212394

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:51:18

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:57
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 15:34:46
User coded data point as SOC: General disorders and administration site conditions, HLGT: Administration site reactions, HLT: Injection site reactions, PT: Injection site pain, LLT: Injection site pain - version MedDRA\\23.0.	Coder Import (b) (4)	12 Oct 2020 18:20:28
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	12 Oct 2020 18:20:28
	(b) (4)	
Data point term sent to Coder	System	12 Oct 2020 18:19:49
User closed query 'For coding purposes, please split INJECTION SITE PAIN AND REDNESS into separate entries.' (Site from System).	System	12 Oct 2020 18:18:59
Query 'For coding purposes, please split INJECTION SITE PAIN AND REDNESS into separate entries.' answered with 'updated' (Site from System).	Afifah Ayub (b) (4)	12 Oct 2020 18:18:59
	(b) (4)	
User entered 'INJECTION SITE PAIN' reason for change: Data Entry Error	Afifah Ayub (b) (4)	12 Oct 2020 18:18:53
	(b) (4)	
User opened query 'For coding purposes, please split INJECTION SITE PAIN AND REDNESS into separate entries.' (Site from System).	Coder Import (b) (4)	08 Oct 2020 11:00:18
	(b) (4)	
Data point term sent to Coder	System	05 Oct 2020 14:15:59
User entered 'INJECTION SITE PAIN AND REDNESS'	Laura Ngansop Djampou (b) (4)	05 Oct 2020 14:15:11

US3212394

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:51:18

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:57
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 15:34:50
User entered 'No (N)'	Laura Ngansop Djampou	05 Oct 2020 14:15:11
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:51:18

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:57
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 15:34:54
User entered 'Yes (Y)'	Laura Ngansop Djampou	05 Oct 2020 14:15:11
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:51:18

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:57
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 15:34:55
User entered 'No (N)'	Laura Ngansop Djampou	05 Oct 2020 14:15:11
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:51:18

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:57
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User closed query 'Per DM CLR - RQ: Site's response noted. However, PC Time stamp does not correspond to the DAY 1 noted on eDiary as DAY 1 should be 11SEP2020. Time stamp only correspond to when the subject entered the information in the eDiary but it should still correspond on the DAY following vaccination (e.g., DAY 1 = 11SEP2020; DAY 2 = 12SEP2020 and so on). Review and update AE start date as appropriate.' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 08:53:55
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 15:35:00
Query 'Per DM CLR - RQ: Site's response noted. However, PC Time stamp does not correspond to the DAY 1 noted on eDiary as DAY 1 should be 11SEP2020. Time stamp only correspond to when the subject entered the information in the eDiary but it should still correspond on the DAY following vaccination (e.g., DAY 1 = 11SEP2020; DAY 2 = 12SEP2020 and so on). Review and update AE start date as appropriate.' answered with 'Amended accordingly' (Site from DM).	Heather Leary (b) (4)	03 Dec 2020 21:26:12
User entered '11 Sep 2020' reason for change: Data Entry Error	(b) (4)	03 Dec 2020 21:26:03
User opened query 'Per DM CLR - RQ: Site's response noted. However, PC Time stamp does not correspond to the DAY 1 noted on eDiary as DAY 1 should be 11SEP2020. Time stamp only correspond to when the subject entered the information in the eDiary but it should still correspond on the DAY following vaccination (e.g., DAY 1 = 11SEP2020; DAY 2 = 12SEP2020 and so on). Review and update AE start date as appropriate.' (Site from DM).	(b) (4), (b) (6)	03 Dec 2020 11:46:25

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:51:18

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please note that this AE start date does not match the Diary initial start date of Solicited Symptom INJECTION SITE PAIN on 11SEP2020. Please review if this should be reconciled. Else, provide clarification on dates.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 20:43:01
Query 'Per DM CLR: Please note that this AE start date does not match the Diary initial start date of Solicited Symptom INJECTION SITE PAIN on 11SEP2020. Please review if this should be reconciled. Else, provide clarification on dates.' answered with 'The date was entered as per the PC Time Stamp of Diary Dose 1 after vaccination (At Home) which shows the 12-SEP-2020 date. ' (Site from DM).	Nirja Shah (b) (4) (b) (4)	02 Nov 2020 18:30:52
User opened query 'Per DM CLR: Please note that this AE start date does not match the Diary initial start date of Solicited Symptom INJECTION SITE PAIN on 11SEP2020. Please review if this should be reconciled. Else, provide clarification on dates.' (Site from DM).	(b) (4), (b) (6)	01 Nov 2020 01:39:13
User closed query 'Adverse Event Start Date is before System 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).		06 Oct 2020 18:23:42
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 Oct 2020 18:23:42
User entered '12 Sep 2020' reason for change: Data Entry Error	Heather Leary (b) (4) (b) (4)	06 Oct 2020 18:23:42
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	05 Oct 2020 14:15:11

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:51:18

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'The Start Date for Adverse Event System 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).		05 Oct 2020 14:15:11
User entered '10 Sep 2020'	Laura Ngansop Djampou (b) (4)	05 Oct 2020 14:15:11

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:51:18

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 06:09:39
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User closed query 'Time entered does not match source. Please remove data and leave blank.' (Site from CRA).	(b) (4), (b) (6)	31 Dec 2020 19:13:07
User closed query 'Per CDM: VID1 = "11 Sept 2020 at 17:00" and AE#1 = "11 Sept 2020". Per page 41 of CCGs V3.0, the start/end time fields are required if start/end time is within 24 hours of dosing. Please update the fields, else clarify. Thank you. (Site from DM).	(b) (4), (b) (6)	22 Dec 2020 20:44:28
Query 'Per CDM: VID1 = "11 Sept 2020 at 17:00" and AE#1 = "11 Sept 2020". Per page 41 of CCGs V3.0, the start/end time fields are required if start/end time is within 24 hours of dosing. Please update the fields, else clarify. Thank you. (Site from DM).	Reagan Reed (b) (4)	18 Dec 2020 15:38:41
User entered '17:00' reason for change: Data Entry Error	Reagan Reed (b) (4)	18 Dec 2020 15:38:34
User opened query 'Per CDM: VID1 = "11 Sept 2020 at 17:00" and AE#1 = "11 Sept 2020". Per page 41 of CCGs V3.0, the start/end time fields are required if start/end time is within 24 hours of dosing. Please update the fields, else clarify. Thank you. (Site from DM).	(b) (4), (b) (6)	18 Dec 2020 15:06:37
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	18 Dec 2020 14:52:54
Query 'Data is required. Please provide.' answered with 'not required did not start within 24 hours of dose' (Site from System).	Reagan Reed (b) (4)	09 Dec 2020 19:50:21
Query 'Time entered does not match source. Please remove data and leave blank.' answered with 'updated' (Site from CRA).	Reagan Reed (b) (4)	09 Dec 2020 19:50:08
User opened query 'Data is required. Please provide.' (Site from System).	System	09 Dec 2020 19:50:02

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:51:18

Start time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Reagan Reed (b) (4)	09 Dec 2020 19:50:02
User opened query 'Time entered does not match source. Please remove data and leave blank.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	08 Dec 2020 15:35:50
User closed query 'Data is required. Please provide.' (Site from System).	System	06 Oct 2020 18:24:24
User entered '07:30' reason for change: Data Entry Error	Heather Leary (b) (4) (b) (4)	06 Oct 2020 18:24:24
User opened query 'Data is required. Please provide.' (Site from System).	System	06 Oct 2020 18:23:42
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	05 Oct 2020 14:15:29
User entered empty; reason for change Data Entry Error	Laura Ngansop Djampou (b) (4)	05 Oct 2020 14:15:29
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	05 Oct 2020 14:15:11
User entered '22:00'	Laura Ngansop Djampou (b) (4)	05 Oct 2020 14:15:11

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:51:18

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:57
User entered '11 Sep 2020 17:00'	System	18 Dec 2020 15:38:34
User entered empty.	System	09 Dec 2020 19:50:02
User entered '11 Sep 2020 07:30'	System	03 Dec 2020 21:26:03
User entered '12 Sep 2020 07:30'	System	06 Oct 2020 18:24:24
User entered empty.	System	05 Oct 2020 14:15:29
User entered '10 Sep 2020 22:00'	System	05 Oct 2020 14:15:11

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:51:18

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:57
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 15:35:54
User entered 'No (N)'	Laura Ngansop Djampou	05 Oct 2020 14:15:11
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:51:18

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:57
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 15:35:57
User entered '19 Sep 2020' reason for change: Data Entry Error	Heather Leary (b) (4)	06 Oct 2020 18:24:24
	(b) (4)	
User entered '18 Sep 2020'	Laura Ngansop Djampou	05 Oct 2020 14:15:11
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:51:18

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:57
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 15:36:00
User closed query 'Per CDM: Please note this field is not required, unless End time is within 24 hours of dosing time. Please review and amend accordingly.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 12:54:28
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	28 Oct 2020 12:53:58
Query 'Data is required. Please provide.' answered with 'Please note this field is not required, unless End time is within 24 hours of dosing time.' (Site from System).	Afifah Ayub (b) (4)	21 Oct 2020 21:25:53
	(b) (4)	
Query 'Per CDM: Please note this field is not required, unless End time is within 24 hours of dosing time. Please review and amend accordingly.' answered with 'updated' (Site from DM).	Afifah Ayub (b) (4)	21 Oct 2020 21:25:47
	(b) (4)	
User opened query 'Data is required. Please provide.' (Site from System).	System	21 Oct 2020 21:25:35
User entered empty; reason for change Data Entry Error	Afifah Ayub (b) (4)	21 Oct 2020 21:25:35
	(b) (4)	
User opened query 'Per CDM: Please note this field is not required, unless End time is within 24 hours of dosing time. Please review and amend accordingly.' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 21:12:09
User closed query 'Data is required. Please provide.' (Site from System).	System	06 Oct 2020 18:24:24
User entered '12:02' reason for change: Data Entry Error	Heather Leary (b) (4)	06 Oct 2020 18:24:24
	(b) (4)	
User opened query 'Data is required. Please provide.' (Site from System).	System	06 Oct 2020 18:23:42
User closed query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	05 Oct 2020 14:15:29
User entered empty; reason for change Data Entry Error	Laura Ngansop Djampou (b) (4)	05 Oct 2020 14:15:29

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:51:18

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User opened query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	05 Oct 2020 14:15:11
User entered '09:00'	Laura Ngansop Djampou (b) (4)	05 Oct 2020 14:15:11

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:51:18

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:57
User entered empty.	System	21 Oct 2020 21:25:35
User entered '19 Sep 2020 12:02'	System	06 Oct 2020 18:24:24
User entered empty.	System	05 Oct 2020 14:15:29
User entered '18 Sep 2020 09:00'	System	05 Oct 2020 14:15:11

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:51:18

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:57
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 15:36:02
User entered 'Grade 1/Mild (Grade 1/Mild)'	Laura Ngansop Djampou	05 Oct 2020 14:15:11
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:51:18

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:57
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 15:36:07
User entered 'No (N)'	Laura Ngansop Djampou	05 Oct 2020 14:15:11
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:51:18

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:57
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 15:39:18
User entered '0'	Laura Ngansop Djampou	05 Oct 2020 14:15:11
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:51:18

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:57
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 15:39:20
User entered '0'	Laura Ngansop Djampou	05 Oct 2020 14:15:11
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:51:18

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:57
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 15:39:32
User entered '0'	Laura Ngansop Djampou	05 Oct 2020 14:15:11
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:51:18

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:57
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 15:39:35
User entered empty.	Laura Ngansop Djampou	05 Oct 2020 14:15:11
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:51:18

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:57
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 15:39:36
User entered empty.	Laura Ngansop Djampou	05 Oct 2020 14:15:11
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:51:18

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:57
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 15:39:38
User entered empty.	Laura Ngansop Djampou	05 Oct 2020 14:15:11
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:51:18

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:57
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 15:39:40
User entered empty.	Laura Ngansop Djampou	05 Oct 2020 14:15:11
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:51:18

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:57
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 15:39:42
User entered '0'	Laura Ngansop Djampou	05 Oct 2020 14:15:11
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:51:18

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:57
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 15:39:44
User entered '0'	Laura Ngansop Djampou	05 Oct 2020 14:15:11
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:51:18

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:57
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 15:39:45
User entered '0'	Laura Ngansop Djampou	05 Oct 2020 14:15:11
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:51:18

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:57
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 15:39:50
User entered 'Related (RELATED)'	Laura Ngansop Djampou	05 Oct 2020 14:15:11
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:51:18

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:57
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 15:39:52
User entered 'Related (RELATED)'	Laura Ngansop Djampou	05 Oct 2020 14:15:11
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:51:18

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:57
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 15:39:55
User entered 'None (NONE)'	Laura Ngansop Djampou	05 Oct 2020 14:15:11
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:51:18

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:57
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:16:25
Signature has been broken.	Heather Leary (b) (4)	16 Apr 2021 15:12:12
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 15:39:58
User closed query 'Per DM CLR: Other Action Taken = None. However, please confirm if CM #2 and 3 were used for this AE. If yes, please review and update this field as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 12:45:57
Query 'Per DM CLR: Other Action Taken = None. However, please confirm if CM #2 and 3 were used for this AE. If yes, please review and update this field as appropriate. Otherwise, clarify.' answered with 'Updated and completed' (Site from DM).	Nirja Shah (b) (4)	02 Nov 2020 19:06:13
User entered '0' reason for change: Per Query Resolution	(b) (4)	02 Nov 2020 19:06:04
User opened query 'Per DM CLR: Other Action Taken = None. However, please confirm if CM #2 and 3 were used for this AE. If yes, please review and update this field as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	01 Nov 2020 01:39:21
User entered '1'	Laura Ngansop Djampou (b) (4)	05 Oct 2020 14:15:11

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:51:18

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:57
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 15:40:00
User entered '1' reason for change: Per Query Resolution	Nirja Shah (b) (4)	02 Nov 2020 19:06:04
	(b) (4)	
User entered '0'	Laura Ngansop Djampou	05 Oct 2020 14:15:11
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:51:18

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:57
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 15:40:03
User entered '0'	Laura Ngansop Djampou	05 Oct 2020 14:15:11
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:51:18

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:57
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 15:40:05
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Laura Ngansop Djampou	05 Oct 2020 14:15:11
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:57
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 15:40:08
User entered empty.	Laura Ngansop Djampou	05 Oct 2020 14:15:11
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:57
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 15:40:10
User entered empty.	Laura Ngansop Djampou	05 Oct 2020 14:15:11
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:51:18

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:57
User entered '0'	System	05 Oct 2020 14:15:11

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:51:18

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:57
User entered '0'	System	05 Oct 2020 14:15:11

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:51:18

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:57

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:51:18

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:04

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:51:18

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:04
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User closed query 'Per DM CLR - RQ: Site's response "'The injection site redness resolved on Day 8 per the Day 8 safety call progress note" noted. However, please clarify if this is present at DAY 8 or the symptom was already absent at DAY 8. If this is not present at DAY 8, then it does not meet the criteria of "ONGOING BEYOND 7 DAYS" per Protocol section 8.3.4 (e.g., eDiary Day 8 - NONE). Please review and update to delete/remove AE as applicable. Otherwise, clarify.' (Site from DM). Query 'Per DM CLR - RQ: Site's response "'The injection site redness resolved on Day 8 per the Day 8 safety call progress note" noted. However, please clarify if this is present at DAY 8 or the symptom was already absent at DAY 8. If this is not present at DAY 8, then it does not meet the criteria of "ONGOING BEYOND 7 DAYS" per Protocol section 8.3.4 (e.g., eDiary Day 8 - NONE). Please review and update to delete/remove AE as applicable. Otherwise, clarify.' answered with 'PER PN IT WAS PRESENT AND RESOLVED ON DAY 8' (Site from DM).	(b) (4), (b) (6)	21 Jan 2021 09:03:04
	Heather Leary (b) (4)	19 Jan 2021 19:40:25
User opened query 'Per DM CLR - RQ: Site's response "'The injection site redness resolved on Day 8 per the Day 8 safety call progress note" noted. However, please clarify if this is present at DAY 8 or the symptom was already absent at DAY 8. If this is not present at DAY 8, then it does not meet the criteria of "ONGOING BEYOND 7 DAYS" per Protocol section 8.3.4 (e.g., eDiary Day 8 - NONE). Please review and update to delete/remove AE as applicable. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 01:52:46

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:51:18

[Adverse event](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR - RQ: Site's response noted. However, please specify if this is URTICARIAL or NON-URTICARIAL. Please update and reconcile with applicable eCRFs so there would be an appropriate match. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	15 Dec 2020 15:07:23
Query 'Per DM CLR - RQ: Site's response noted. However, please specify if this is URTICARIAL or NON-URTICARIAL. Please update and reconcile with applicable eCRFs so there would be an appropriate match. Otherwise, clarify.' answered with 'unknown' (Site from DM).	Reagan Reed (b) (4)	09 Dec 2020 19:49:36
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 15:43:50
User opened query 'Per DM CLR - RQ: Site's response noted. However, please specify if this is URTICARIAL or NON-URTICARIAL. Please update and reconcile with applicable eCRFs so there would be an appropriate match. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	03 Dec 2020 11:40:01
User closed query 'Per DM CLR: Please review AE and please update to specify the anatomical location (e.g., Right Arm, Left Arm, etc), Type of REDNESS (e.g. Maculopapular, Pustular, etc.) and if this is URTICARIAL or NON-URTICARIAL. Please update and reconcile with applicable eCRFs so there would be an appropriate match. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 20:45:02
User closed query 'Per DM CLR: Please note that solicited reactions are only to reported as AE if this meets AE reporting criteria per protocol 8.3.4 (e.g, Lasting for more than 7 days post injection). Please review if recorded event meets criteria (i.e., eDiary INJECTION SITE REDNESS Day 8 = NO). Please review and confirm if INJECTION SITE REDNESS is present at Day 8. Else, consider deleting event as this has been captured in Diary Data. Otherwise, confirm that this symptom is present at DAY 8 or confirm this is unsolicited event per investigator.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 20:44:38

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Folder: Adverse Events

Form: Adverse Events (3)

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[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: General disorders and administration site conditions, HLGT: Administration site reactions, HLT: Injection site reactions, PT: Injection site erythema, LLT: Injection site erythema - version MedDRA\\23.0.	Coder Import (b) (4)	10 Nov 2020 16:11:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Nov 2020 16:11:37
Data point term sent to Coder	System	10 Nov 2020 16:10:31
Query 'Per DM CLR: Please review AE and please update to specify the anatomical location (e.g., Right Arm, Left Arm, etc), Type of REDNESS (e.g. Maculopapular, Pustular, etc.) and if this is URTICARIAL or NON-URTICARIAL. Please update and reconcile with applicable eCRFs so there would be an appropriate match. Otherwise, clarify.'	Reagan Reed (b) (4)	10 Nov 2020 16:10:22
answered with 'updated per protocol ' (Site from DM).	(b) (4)	
Coding entries removed.	Reagan Reed (b) (4)	10 Nov 2020 16:10:14
User entered 'INJECTION SITE erythema' reason for change: Data Entry Error	(b) (4)	
Query 'Per DM CLR: Please note that solicited reactions are only to reported as AE if this meets AE reporting criteria per protocol 8.3.4 (e.g, Lasting for more than 7 days post injection). Please review if recorded event meets criteria (i.e., eDiary INJECTION SITE REDNESS Day 8 = NO). Please review and confirm if INJECTION SITE REDNESS is present at Day 8. Else, consider deleting event as this has been captured in Diary Data. Otherwise, confirm that this symptom is present at DAY 8 or confirm this is unsolicited event per investigator.'	Reagan Reed (b) (4)	10 Nov 2020 16:10:14
answered with 'The injection site redness resolved on Day 8 per the Day 8 safety call progress note. ' (Site from DM).	(b) (4)	
	Nirja Shah (b) (4)	02 Nov 2020 19:28:20
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:51:18

[Adverse event](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that solicited reactions are only to reported as AE if this meets AE reporting criteria per protocol 8.3.4 (e.g, Lasting for more than 7 days post injection). Please review if recorded event meets criteria (i.e., eDiary INJECTION SITE REDNESS Day 8 = NO). Please review and confirm if INJECTION SITE REDNESS is present at Day 8. Else, consider deleting event as this has been captured in Diary Data. Otherwise, confirm that this symptom is present at DAY 8 or confirm this is unsolicited event per investigator.' (Site from DM).	(b) (4), (b) (6)	01 Nov 2020 01:40:36
User opened query 'Per DM CLR: Please review AE and please update to specify the anatomical location (e.g., Right Arm, Left Arm, etc), Type of REDNESS (e.g. Maculopapular, Pustular, etc.) and if this is URTICARIAL or NON-URTICARIAL. Please update and reconcile with applicable eCRFs so there would be an appropriate match. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	01 Nov 2020 01:40:14
User coded data point as SOC: General disorders and administration site conditions, HLGT: Administration site reactions, HLT: Injection site reactions, PT: Injection site erythema, LLT: Injection site redness - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Oct 2020 15:24:15
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Oct 2020 15:24:15
Data point term sent to Coder	System	12 Oct 2020 15:23:42
User entered 'INJECTION SITE REDNESS'	Laura Ngansop Djampou (b) (4)	12 Oct 2020 15:23:35

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:51:18

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:04
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 15:43:56
User entered 'No (N)'	Laura Ngansop Djampou	12 Oct 2020 15:23:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:51:18

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:04
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:23:51
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User closed query 'Per CDM: Note, Was this medication taken for solicited event?' = NO. However, the Indication reported is included as one of the solicited AEs per protocol. Review and update entry as appropriate. Otherwise,' (Site from DM). Query 'Per CDM: Note, Was this medication taken for solicited event?' = NO. However, the Indication reported is included as one of the solicited AEs per protocol. Review and update entry as appropriate. Otherwise,' answered with 'updated, AE is solicited AR' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 12:47:44
User entered 'Yes (Y)' reason for change: Data Entry Error	Heather Leary (b) (4)	22 Oct 2020 14:12:21
User opened query 'Per CDM: Note, Was this medication taken for solicited event?' = NO. However, the Indication reported is included as one of the solicited AEs per protocol. Review and update entry as appropriate. Otherwise,' (Site from DM). User entered 'No (N)'	(b) (4), (b) (6)	22 Oct 2020 07:45:37
	Laura Ngansop Djampou (b) (4)	12 Oct 2020 15:23:35

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:51:18

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:04
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 15:44:01
User entered 'No (N)'	Laura Ngansop Djampou	12 Oct 2020 15:23:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:51:18

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:04
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 15:44:04
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	13 Oct 2020 21:04:43
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	13 Oct 2020 21:04:43
User entered '12 Sep 2020' reason for change: Data Entry Error	Heather Leary (b) (4)	13 Oct 2020 21:04:43
	(b) (4)	
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	12 Oct 2020 15:23:35
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	12 Oct 2020 15:23:35
User entered '10 Sep 2020'	Laura Ngansop Djampou (b) (4)	12 Oct 2020 15:23:35

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:51:18

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:04
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 15:44:05
User closed query 'Data is required. Please provide.' (Site from System).	System	13 Oct 2020 21:04:59
User entered '09:30' reason for change: Data Entry Error	Heather Leary (b) (4)	13 Oct 2020 21:04:59
	(b) (4)	
User opened query 'Data is required. Please provide.' (Site from System).	System	13 Oct 2020 21:04:43
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	12 Oct 2020 18:19:27
User entered empty; reason for change Data Entry Error	Afifah Ayub (b) (4)	12 Oct 2020 18:19:27
	(b) (4)	
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	12 Oct 2020 15:25:15
User entered '09:30' reason for change: Data Entry Error	Laura Ngansop Djampou	12 Oct 2020 15:25:15
	(b) (4)	
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	12 Oct 2020 15:23:58
User entered empty; reason for change Data Entry Error	Laura Ngansop Djampou	12 Oct 2020 15:23:58
	(b) (4)	
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	12 Oct 2020 15:23:35
User entered '09:30'	Laura Ngansop Djampou	12 Oct 2020 15:23:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:51:18

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:04
User entered '12 Sep 2020 09:30'	System	13 Oct 2020 21:04:59
User entered empty.	System	12 Oct 2020 18:19:27
User entered '10 Sep 2020 09:30'	System	12 Oct 2020 15:25:15
User entered empty.	System	12 Oct 2020 15:23:58
User entered '10 Sep 2020 09:30'	System	12 Oct 2020 15:23:35

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:51:18

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:04
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 15:44:09
User entered 'No (N)'	Laura Ngansop Djampou	12 Oct 2020 15:23:35
	(b) (4)	

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Form: Adverse Events (3)

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:04
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 15:44:13
User entered '18 Sep 2020'	Laura Ngansop Djampou	12 Oct 2020 15:23:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:51:18

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:04
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 15:44:15
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	23 Nov 2020 20:44:46
User closed query 'Per CDM: As per CCG, End time is not required, for an AE that did not end within 24 hours of dosing. Please review & update accordingly, else clarify.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 20:44:44
Query 'Data is required. Please provide.' answered with 'updated' (Site from System).	Reagan Reed (b) (4)	18 Nov 2020 15:40:14
Query 'Per CDM: As per CCG, End time is not required, for an AE that did not end within 24 hours of dosing. Please review & update accordingly, else clarify.' answered with 'updated' (Site from DM).	Reagan Reed (b) (4)	18 Nov 2020 15:39:48
User opened query 'Data is required. Please provide.' (Site from System).	System	18 Nov 2020 15:39:22
User entered empty; reason for change Data Entry Error	Reagan Reed (b) (4)	18 Nov 2020 15:39:22
User opened query 'Per CDM: As per CCG, End time is not required, for an AE that did not end within 24 hours of dosing. Please review & update accordingly, else clarify.' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 11:55:16
User closed query 'Data is required. Please provide.' (Site from System).	System	13 Oct 2020 21:05:12
User entered '16:15' reason for change: Data Entry Error	Heather Leary (b) (4)	13 Oct 2020 21:05:12
User opened query 'Data is required. Please provide.' (Site from System).	System	13 Oct 2020 21:04:43
User closed query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	12 Oct 2020 18:19:27
User entered empty; reason for change Data Entry Error	Afifah Ayub (b) (4)	12 Oct 2020 18:19:27
User opened query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	12 Oct 2020 15:25:15

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EAB) (1725)

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End time (00:00-23:59)

Audit	User	Time (GMT)
User entered '16:15' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	12 Oct 2020 15:25:15
User closed query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	12 Oct 2020 15:23:58
User entered empty; reason for change Data Entry Error	Laura Ngansop Djampou (b) (4)	12 Oct 2020 15:23:58
User opened query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	12 Oct 2020 15:23:35
User entered '16:15'	Laura Ngansop Djampou (b) (4)	12 Oct 2020 15:23:35

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[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:04
User entered empty.	System	18 Nov 2020 15:39:22
User entered '18 Sep 2020 16:15'	System	13 Oct 2020 21:05:12
User entered empty.	System	12 Oct 2020 18:19:27
User entered '18 Sep 2020 16:15'	System	12 Oct 2020 15:25:15
User entered empty.	System	12 Oct 2020 15:23:58
User entered '18 Sep 2020 16:15'	System	12 Oct 2020 15:23:35

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[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:04
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 15:44:28
User entered 'Grade 1/Mild (Grade 1/Mild)'	Laura Ngansop Djampou	12 Oct 2020 15:23:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:04
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 15:45:49
User entered 'No (N)'	Laura Ngansop Djampou	12 Oct 2020 15:23:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

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[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:04
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 15:45:51
User entered '0'	Laura Ngansop Djampou	12 Oct 2020 15:23:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:51:18

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:04
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 15:45:53
User entered '0'	Laura Ngansop Djampou	12 Oct 2020 15:23:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:51:18

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:04
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 15:45:54
User entered '0'	Laura Ngansop Djampou	12 Oct 2020 15:23:35
	(b) (4)	

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Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:51:18

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:04
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 15:45:56
User entered empty.	Laura Ngansop Djampou	12 Oct 2020 15:23:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:51:18

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:04
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 15:45:58
User entered empty.	Laura Ngansop Djampou	12 Oct 2020 15:23:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:04
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 15:46:00
User entered empty.	Laura Ngansop Djampou	12 Oct 2020 15:23:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:04
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 15:46:01
User entered empty.	Laura Ngansop Djampou	12 Oct 2020 15:23:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:04
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 15:46:03
User entered '0'	Laura Ngansop Djampou	12 Oct 2020 15:23:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:51:18

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:04
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 15:46:05
User entered '0'	Laura Ngansop Djampou	12 Oct 2020 15:23:35
	(b) (4)	

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:04
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 15:46:07
User entered '0'	Laura Ngansop Djampou	12 Oct 2020 15:23:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:04
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 15:46:12
User entered 'Related (RELATED)'	Laura Ngansop Djampou	12 Oct 2020 15:23:35
	(b) (4)	

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:04
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:23:55
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:16:25
DataPoint Un-verified.	Heather Leary (b) (4)	16 Apr 2021 15:12:28
Signature has been broken.	Heather Leary (b) (4)	16 Apr 2021 15:12:28
User entered 'Related (RELATED)' reason for change: Data Entry Error	Heather Leary (b) (4)	16 Apr 2021 15:12:28
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:29:33
User closed query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you. ' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 20:44:50
Query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you. ' answered with 'updated' (Site from DM).	Reagan Reed (b) (4)	18 Nov 2020 15:40:45
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Reagan Reed (b) (4)	18 Nov 2020 15:39:41
User opened query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you. ' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 06:01:07
User entered 'Not Applicable (NOT APPLICABLE)'	Laura Ngansop Djampou (b) (4)	12 Oct 2020 15:23:35

US3212394

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:51:18

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:04
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 15:46:18
User entered 'None (NONE)'	Laura Ngansop Djampou	12 Oct 2020 15:23:35
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:51:18

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:04
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 15:46:23
User entered 'l'	Laura Ngansop Djampou	12 Oct 2020 15:23:35
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:51:18

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:04
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 15:46:26
User entered '0'	Laura Ngansop Djampou	12 Oct 2020 15:23:35
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:51:18

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:04
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 15:46:27
User entered '0'	Laura Ngansop Djampou	12 Oct 2020 15:23:35
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:51:18

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:04
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 15:46:33
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Laura Ngansop Djampou (b) (4)	12 Oct 2020 15:23:35

US3212394

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:51:18

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:04
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 15:46:39
User entered empty.	Laura Ngansop Djampou	12 Oct 2020 15:23:35
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:51:18

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:04
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 15:46:42
User entered empty.	Laura Ngansop Djampou	12 Oct 2020 15:23:35
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:51:18

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:04
User entered '0'	System	12 Oct 2020 15:23:35

US3212394

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:51:18

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:04
User entered '0'	System	12 Oct 2020 15:23:35

US3212394

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:51:18

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:04

US3212394

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:51:18

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:11

US3212394

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:51:18

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:11
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 15:47:28
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Ear infections, PT: Otitis media, LLT: Otitis media - version MedDRA\\23.0.	Coder Import (b) (4)	16 Nov 2020 14:54:42
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	16 Nov 2020 14:54:42
	(b) (4)	
Data point term sent to Coder	System	16 Nov 2020 14:25:09
User entered 'Otitis Media in right ear'	Laura Ngansop Djampou	16 Nov 2020 14:24:53
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:51:18

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:11
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 15:47:32
User entered 'Yes (Y)'	Laura Ngansop Djampou	16 Nov 2020 14:24:53
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:51:18

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:11
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:29:37
User entered 'No (N)'	Laura Ngansop Djampou	16 Nov 2020 14:24:53
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:51:18

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:11
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 15:47:39
User entered 'No (N)'	Laura Ngansop Djampou	16 Nov 2020 14:24:53
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:51:18

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:11
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 15:47:43
User entered '02 Nov 2020' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	07 Dec 2020 20:15:01
User entered '2 Nov 2020'	Laura Ngansop Djampou (b) (4)	16 Nov 2020 14:24:53

US3212394

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:51:18

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:11
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 15:47:45
User entered empty.	Laura Ngansop Djampou	16 Nov 2020 14:24:53
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:51:18

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:11
User entered empty.	System	16 Nov 2020 14:24:53

US3212394

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:51:18

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:11
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 06:14:00
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User closed query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing.' (Site from DM).	(b) (4), (b) (6)	21 Jan 2021 09:04:22
Query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing.' answered with 'UPDATED' (Site from DM).	Heather Leary (b) (4)	19 Jan 2021 19:38:35
DataPoint Un-verified.	Heather Leary (b) (4)	19 Jan 2021 19:38:27
User entered 'No (N)' reason for change: Data Entry Error	Heather Leary (b) (4)	19 Jan 2021 19:38:27
User opened query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing.' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 01:52:59
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 15:47:47
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	16 Nov 2020 14:24:53

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:51:18

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:11
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 06:14:02
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Un-verified.	Heather Leary (b) (4)	19 Jan 2021 19:38:27
	(b) (4)	
User entered '18 Nov 2020' reason for change: Data Entry Error	Heather Leary (b) (4)	19 Jan 2021 19:38:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 15:47:49
User entered empty.	Laura Ngansop Djampou	16 Nov 2020 14:24:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:51:18

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:11
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 15:47:50
User entered empty.	Laura Ngansop Djampou	16 Nov 2020 14:24:53
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:51:18

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:11
User entered empty.	System	16 Nov 2020 14:24:53

US3212394

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:51:18

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:11
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 15:47:52
User entered 'Grade 1/Mild (Grade 1/Mild)'	Laura Ngansop Djampou	16 Nov 2020 14:24:53
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:51:18

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:11
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 15:47:58
User entered 'No (N)'	Laura Ngansop Djampou	16 Nov 2020 14:24:53
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:51:18

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:11
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 15:48:00
User entered '0'	Laura Ngansop Djampou	16 Nov 2020 14:24:53
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:51:18

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:11
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 15:48:01
User entered '0'	Laura Ngansop Djampou	16 Nov 2020 14:24:53
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:51:18

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:11
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 15:48:03
User entered '0'	Laura Ngansop Djampou	16 Nov 2020 14:24:53
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:51:18

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:11
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 15:48:04
User entered empty.	Laura Ngansop Djampou	16 Nov 2020 14:24:53
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:51:18

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:11
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 15:48:07
User entered empty.	Laura Ngansop Djampou	16 Nov 2020 14:24:53
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:51:18

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:11
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 15:48:10
User entered empty.	Laura Ngansop Djampou	16 Nov 2020 14:24:53
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:51:18

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:11
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 15:48:11
User entered empty.	Laura Ngansop Djampou	16 Nov 2020 14:24:53
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:51:18

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:11
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 15:48:13
User entered '0'	Laura Ngansop Djampou	16 Nov 2020 14:24:53
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:51:18

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:11
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 15:48:16
User entered '0'	Laura Ngansop Djampou	16 Nov 2020 14:24:53
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:51:18

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:11
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 15:48:18
User entered '0'	Laura Ngansop Djampou	16 Nov 2020 14:24:53
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:51:18

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:11
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 15:48:22
User entered 'Not Related (NOT RELATED)'	Laura Ngansop Djampou (b) (4)	16 Nov 2020 14:24:53

US3212394

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:51:18

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:11
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:29:40
User closed query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you. ' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 20:45:24
Query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you. ' answered with 'updated' (Site from DM).	Reagan Reed (b) (4) (b) (4)	18 Nov 2020 15:40:31
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Reagan Reed (b) (4) (b) (4)	18 Nov 2020 15:40:25
User opened query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you. ' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 06:01:48
User entered 'Not Applicable (NOT APPLICABLE)'	Laura Ngansop Djampou (b) (4)	16 Nov 2020 14:24:53

US3212394

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:51:18

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:11
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 15:48:30
User entered 'Not Applicable (NOT APPLICABLE)'	Laura Ngansop Djampou (b) (4)	16 Nov 2020 14:24:53

US3212394

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:51:18

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:11
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:16:25
	(b) (4)	
User closed query 'Per source, no action was taken. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 17:54:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:53:49
Query 'Per source, no action was taken. Please verify and update accordingly.' answered with 'updated' (Site from CRA).	Heather Leary (b) (4)	16 Apr 2021 13:26:09
	(b) (4)	
Signature has been broken.	Heather Leary (b) (4)	16 Apr 2021 13:25:53
	(b) (4)	
User entered '1' reason for change: Data Entry Error	Heather Leary (b) (4)	16 Apr 2021 13:25:53
	(b) (4)	
User opened query 'Per source, no action was taken. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 06:14:41
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Un-verified.	Reagan Reed (b) (4)	09 Dec 2020 19:48:25
	(b) (4)	
User entered '0' reason for change: Data Entry Error	Reagan Reed (b) (4)	09 Dec 2020 19:48:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 15:48:35
User entered '1'	Laura Ngansop Djampou (b) (4)	16 Nov 2020 14:24:53

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:51:18

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:11
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:16:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 17:54:19
Signature has been broken.	Heather Leary (b) (4)	16 Apr 2021 13:25:53
	(b) (4)	
User entered '0' reason for change: Data Entry Error	Heather Leary (b) (4)	16 Apr 2021 13:25:53
	(b) (4)	
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Un-verified.	Reagan Reed (b) (4)	09 Dec 2020 19:48:25
	(b) (4)	
User entered '1' reason for change: Data Entry Error	Reagan Reed (b) (4)	09 Dec 2020 19:48:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 15:49:03
User entered '0'	Laura Ngansop Djampou	16 Nov 2020 14:24:53
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:51:18

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:11
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 15:49:05
User entered '0'	Laura Ngansop Djampou	16 Nov 2020 14:24:53
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:51:18

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:11
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 06:14:45
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Un-verified.	Heather Leary (b) (4)	19 Jan 2021 19:38:27
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Heather Leary (b) (4)	19 Jan 2021 19:38:27
Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 15:49:08
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Laura Ngansop Djampou (b) (4)	16 Nov 2020 14:24:53

US3212394

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:51:18

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:11
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 15:49:10
User entered empty.	Laura Ngansop Djampou	16 Nov 2020 14:24:53
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:51:18

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:11
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 15:49:11
User entered empty.	Laura Ngansop Djampou	16 Nov 2020 14:24:53
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:51:18

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:11
User entered '0'	System	16 Nov 2020 14:24:53

US3212394

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:51:18

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:11
User entered '1'	System	16 Nov 2020 14:24:53

US3212394

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:51:18

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:11

US3212394

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:51:18

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	10 Dec 2020 15:04:03
Un-reviewed for Safety.	(b) (4), (b) (6)	10 Dec 2020 15:03:59
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 15:49:19
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:03:10
User entered	System	30 Nov 2020 16:03:01
'USA-US115-2020-mRNA-1273-P301000014'		
User entered 'New'	(b) (4), (b) (6)	30 Nov 2020 16:03:01

US3212394

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:51:18

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
	(b) (4), (b) (6)	10 Dec 2020 15:01:41
User closed query 'PV Query: Dyspnea is a symptom of a medical condition. Kindly consider updating the event verbatim with a more specific diagnosis/medical condition.' (Site from Safety). Query 'PV Query: Dyspnea is a symptom of a medical condition. Kindly consider updating the event verbatim with a more specific diagnosis/medical condition.' answered with 'This was the condition that caused subject to be admitted to the hospital. No diagnosis given. Per PI Dyspnea still the SAE term and condition. ' (Site from Safety). DataPoint Verified.	Reagan Reed (b) (4)	09 Dec 2020 19:54:42
	(b) (4), (b) (6)	08 Dec 2020 15:58:40
User opened query 'PV Query: Dyspnea is a symptom of a medical condition. Kindly consider updating the event verbatim with a more specific diagnosis/medical condition.' (Site from Safety). User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory disorders NEC, HLT: Breathing abnormalities, PT: Dyspnoea, LLT: Dyspnea - version MedDRA\\23.0. User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. Data point term sent to Coder Coding entries removed.	(b) (4), (b) (6)	04 Dec 2020 20:06:28
	Coder Import (b) (4)	25 Nov 2020 21:34:07
	Coder Import (b) (4)	25 Nov 2020 21:34:07
	System	25 Nov 2020 21:33:23
	Reagan Reed (b) (4)	25 Nov 2020 21:33:07
User entered 'Dyspnea' reason for change: Data Entry Error	Reagan Reed (b) (4)	25 Nov 2020 21:33:07
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory disorders NEC, HLT: Breathing abnormalities, PT: Dyspnoea, LLT: Shortness of breath - version MedDRA\\23.0. User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. Data point term sent to Coder User entered 'Shortness of Breath'	Coder Import (b) (4)	25 Nov 2020 21:07:18
	Coder Import (b) (4)	25 Nov 2020 21:07:18
	System	25 Nov 2020 21:05:53
	Afifah Ayub (b) (4)	25 Nov 2020 21:05:02

US3212394

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:51:18

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 15:58:51
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	25 Nov 2020 21:05:02
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:51:18

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) [REDACTED]	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6) [REDACTED]	23 Dec 2020 22:29:45
User entered 'No (N)'	Afifah Ayub (b) (4) (b) (4)	25 Nov 2020 21:05:02

US3212394

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:51:18

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 15:59:05
User entered 'No (N)'	Afifah Ayub (b) (4)	25 Nov 2020 21:05:02
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:51:18

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:30:06
DataPoint Un-verified.	Reagan Reed (b) (4)	09 Dec 2020 19:55:27
	(b) (4)	
User entered '15 Nov 2020' reason for change: Data Entry Error	Reagan Reed (b) (4)	09 Dec 2020 19:55:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 15:59:08
User entered '19 Nov 2020'	Afifah Ayub (b) (4)	25 Nov 2020 21:05:02
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:51:18

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 15:59:10
User entered empty.	Afifah Ayub (b) (4)	25 Nov 2020 21:05:02
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:51:18

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Nov 2020 21:05:02

US3212394

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:51:18

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 15:59:11
User entered 'No (N)' reason for change: New Information	Heather Leary (b) (4)	25 Nov 2020 21:52:40
	(b) (4)	
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	25 Nov 2020 21:05:02
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:51:18

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 06:15:21
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User closed query 'Per source, AE ended 23Nov20. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	31 Dec 2020 19:14:53
Query 'Per source, AE ended 23Nov20. Please verify and update accordingly.' answered with 'source updated to reflect stop time of Azithromycin used to manage the dyspnea. Azithromycin ended 30NOV2020' (Site from CRA).	Reagan Reed (b) (4)	29 Dec 2020 14:59:17
User opened query 'Per source, AE ended 23Nov20. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	23 Dec 2020 22:31:18
DataPoint Un-verified.	Reagan Reed (b) (4)	09 Dec 2020 19:57:16
User entered '30 Nov 2020' reason for change: New Information	Reagan Reed (b) (4)	09 Dec 2020 19:57:16
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 15:59:13
User entered '23 Nov 2020' reason for change: New Information	Heather Leary (b) (4)	25 Nov 2020 21:52:40
User entered empty.	Afifah Ayub (b) (4)	25 Nov 2020 21:05:02

US3212394

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:51:18

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 15:59:15
User closed query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	25 Nov 2020 21:53:19
User entered empty; reason for change Data Entry Error	Heather Leary (b) (4)	25 Nov 2020 21:53:19
	(b) (4)	
User opened query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	25 Nov 2020 21:52:40
User entered '08:00' reason for change: Data Entry Error	Heather Leary (b) (4)	25 Nov 2020 21:52:40
	(b) (4)	
User entered empty.	Afifah Ayub (b) (4)	25 Nov 2020 21:05:02
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:51:18

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Nov 2020 21:53:19
User entered '23 Nov 2020 08:00'	System	25 Nov 2020 21:52:40
User entered empty.	System	25 Nov 2020 21:05:02

US3212394

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:51:18

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 15:59:16
User entered 'Grade 3/Severe (Grade 3/Severe)'	Afifah Ayub (b) (4)	25 Nov 2020 21:05:02
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:51:18

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 15:59:19
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	25 Nov 2020 21:05:02
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:51:18

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 15:59:23
User entered '0'	Afifah Ayub (b) (4)	25 Nov 2020 21:05:02
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:51:18

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 15:59:27
User entered '0'	Afifah Ayub (b) (4)	25 Nov 2020 21:05:02
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:51:18

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 15:59:29
User entered 'I'	Afifah Ayub (b) (4)	25 Nov 2020 21:05:02
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:51:18

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
	(b) (4), (b) (6)	
User closed query 'PV Query: Please clarify the start date of 19 Nov as the narrative reports dyspnea starting on 15 Nov. Please update to date of onset of symptoms.' (Site from Safety).		10 Dec 2020 15:02:22
Query 'PV Query: Please clarify the start date of 19 Nov as the narrative reports dyspnea starting on 15 Nov. Please update to date of onset of symptoms.' answered with 'updated' (Site from Safety).	Reagan Reed (b) (4)	09 Dec 2020 19:55:35
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 15:59:31
User opened query 'PV Query: Please clarify the start date of 19 Nov as the narrative reports dyspnea starting on 15 Nov. Please update to date of onset of symptoms.' (Site from Safety).	(b) (4), (b) (6)	04 Dec 2020 20:06:59
User entered '19 Nov 2020'	Afifah Ayub (b) (4)	25 Nov 2020 21:05:02
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:51:18

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
	(b) (4), (b) (6)	
User closed query 'PV Query: Please clarify the event end date of 23 Nov 2020 as the subject was started on a new antibiotic on 25 Nov 2020 for dyspnea.' (Site from Safety).		10 Dec 2020 15:03:22
Query 'PV Query: Please clarify the event end date of 23 Nov 2020 as the subject was started on a new antibiotic on 25 Nov 2020 for dyspnea.' answered with 'updated' (Site from Safety).	Reagan Reed (b) (4)	09 Dec 2020 19:57:22
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 16:00:11
User opened query 'PV Query: Please clarify the event end date of 23 Nov 2020 as the subject was started on a new antibiotic on 25 Nov 2020 for dyspnea.' (Site from Safety).	(b) (4), (b) (6)	04 Dec 2020 20:07:10
User entered '20 Nov 2020'	Afifah Ayub (b) (4)	25 Nov 2020 21:05:02
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:51:18

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) [REDACTED]	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6) [REDACTED]	08 Dec 2020 16:00:47
User entered 'No (N)'	Afifah Ayub (b) (4) (b) (4)	25 Nov 2020 21:05:02

US3212394

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:51:18

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 16:00:49
User entered empty.	Afifah Ayub (b) (4)	25 Nov 2020 21:05:02
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:51:18

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 16:00:51
User entered '0'	Afifah Ayub (b) (4)	25 Nov 2020 21:05:02
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:51:18

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 16:00:54
User entered '0'	Afifah Ayub (b) (4)	25 Nov 2020 21:05:02
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:51:18

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 16:00:57
User entered '0'	Afifah Ayub (b) (4)	25 Nov 2020 21:05:02
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:51:18

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 16:01:03
User entered 'Not Related (NOT RELATED)'	Afifah Ayub (b) (4)	25 Nov 2020 21:05:02
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:51:18

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:31:41
User entered 'Not Related (NOT RELATED)'	Afifah Ayub (b) (4)	25 Nov 2020 21:05:02
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:51:18

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 16:01:07
User entered 'Not Applicable (NOT APPLICABLE)'	Afifah Ayub (b) (4)	25 Nov 2020 21:05:02
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:51:18

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 16:01:09
User entered '0'	Afifah Ayub (b) (4)	25 Nov 2020 21:05:02
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:51:18

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 16:01:11
User entered 'I'	Afifah Ayub (b) (4)	25 Nov 2020 21:05:02
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:51:18

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 16:01:13
User entered '0'	Afifah Ayub (b) (4)	25 Nov 2020 21:05:02
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:51:18

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 16:01:16
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Heather Leary (b) (4)	25 Nov 2020 21:52:40
New Information	(b) (4)	
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Afifah Ayub (b) (4)	25 Nov 2020 21:05:02
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:51:18

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 16:01:25
User entered empty.	Afifah Ayub (b) (4)	25 Nov 2020 21:05:02
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:51:18

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User closed query 'Per DM CLR: Per Narrative "SHE WAS DISCHARGED HOME ON ANTIBIOTICS AND AN INHALER". However, among the medictaions recorded in the CM page. There is no single medication given via oral inhalation. Please review and update to reconcile as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	03 Feb 2021 11:55:31
User closed query 'Per DM CLR: Chest X-ray was noted in the SAE Narrative. However, this procedure is not recorded in the ConProc page. Please review and update to reconcile as appropriate. Otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	03 Feb 2021 11:53:19
Query 'Per DM CLR: Per Narrative "SHE WAS DISCHARGED HOME ON ANTIBIOTICS AND AN INHALER". However, among the medictaions recorded in the CM page. There is no single medication given via oral inhalation. Please review and update to reconcile as appropriate. Otherwise, provide clarification.' answered with 'Zithromax is an antibiotic and Levaquin is an inhaler. please see med log. ' (Site from DM).	Reagan Reed (b) (4) (b) (4)	02 Feb 2021 16:28:51
Query 'Per DM CLR: Chest X-ray was noted in the SAE Narrative. However, this procedure is not recorded in the ConProc page. Please review and update to reconcile as appropriate. Otherwise provide clarification.' answered with 'entered' (Site from DM).	Reagan Reed (b) (4) (b) (4)	02 Feb 2021 16:26:17
User opened query 'Per DM CLR: Per Narrative "SHE WAS DISCHARGED HOME ON ANTIBIOTICS AND AN INHALER". However, among the medictaions recorded in the CM page. There is no single medication given via oral inhalation. Please review and update to reconcile as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 15:58:53

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:51:18

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Chest X-ray was noted in the SAE Narrative. However, this procedure is not recorded in the ConProc page. Please review and update to reconcile as appropriate. Otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 15:58:00
User closed query 'PV Query: Please confirm if tachycardia, black stools and stomachache meet criteria for separate AE/SAE reporting.' (Site from Safety).	(b) (4), (b) (6)	10 Dec 2020 15:03:53
Query 'PV Query: Please confirm if tachycardia, black stools and stomachache meet criteria for separate AE/SAE reporting.' answered with 'AE log reflects all AE's' (Site from Safety).	Reagan Reed (b) (4)	09 Dec 2020 20:09:46
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 16:06:55
User opened query 'PV Query: Please confirm if tachycardia, black stools and stomachache meet criteria for separate AE/SAE reporting.' (Site from Safety).	(b) (4), (b) (6)	04 Dec 2020 20:06:39
User entered 'Subject was admitted to the hospital for shortness of breath on 19NOV2020 and Discharged 20NOV2020 subject confirmed her admittance lasted for 24 hours or more. She was admitted to hospital for one day starting Nov. 19. She had black stool, burping and stomach ache starting Nov12. By Nov. 15 her most prominent symptoms were fatigue, dyspnea and tachycardia. She could feel her heart racing especially with activity. Nov 19 she was seen in the ER with tachycardia and dyspnea. Her oxygen saturation wasn't significantly low. CT didn't show any pneumonia or PE. She was started on antibiotics for possible small infiltrate on CXR. She said she a had a low grade fever to 100.7 at the highest. Her Covid testing was negative. No significant anemia. She was discharged home on antibiotics and an inhaler. She feels much better now. She still has some fatigue. She has mild tachycardia when she walks. Her pulse was 117 when walking around today. She denies dizziness. Will continue to follow her.' reason for change: Data Entry Error	Reagan Reed (b) (4)	25 Nov 2020 21:41:37

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:51:18

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	25 Nov 2020 21:05:25
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	25 Nov 2020 21:05:25
User entered 'Subject was admitted to the hospital for shortness of breath on 19NOV2020 and Discharged 20NOV2020 subject confirmed her admittance lasted for 24 hours or more.' reason for change: Data Entry Error	Afifah Ayub (b) (4)	25 Nov 2020 21:05:25
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	25 Nov 2020 21:05:02
User entered empty.	Afifah Ayub (b) (4)	25 Nov 2020 21:05:02

US3212394

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:51:18

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Nov 2020 21:05:02

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:51:18

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	25 Nov 2020 21:05:02

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:51:18

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	25 Nov 2020 21:05:02

US3212394

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:51:18

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:17

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:51:18

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:17
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 16:09:09
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Rate and rhythm disorders NEC, PT: Tachycardia, LLT: Tachycardia - version MedDRA\\23.0.	Coder Import (b) (4)	25 Nov 2020 21:07:18
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	25 Nov 2020 21:07:18
	(b) (4)	
Data point term sent to Coder	System	25 Nov 2020 21:06:54
User entered 'tachycardia'	Afifah Ayub (b) (4)	25 Nov 2020 21:06:28
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:51:18

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:17
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 16:09:20
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	25 Nov 2020 21:06:28
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:51:18

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:17
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:31:55
User entered 'No (N)'	Afifah Ayub (b) (4)	25 Nov 2020 21:06:28
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:51:18

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:17
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 16:09:26
User entered 'No (N)'	Afifah Ayub (b) (4)	25 Nov 2020 21:06:28
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:51:18

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:17
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 16:09:28
User entered '15 Nov 2020'	Afifah Ayub (b) (4)	25 Nov 2020 21:06:28
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:51:18

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:17
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 16:09:30
User entered empty.	Afifah Ayub (b) (4)	25 Nov 2020 21:06:28
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:51:18

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:17
User entered empty.	System	25 Nov 2020 21:06:28

US3212394

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:51:18

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:17
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:32:04
DataPoint Un-verified.	Afifah Ayub (b) (4)	13 Dec 2020 19:30:25
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	13 Dec 2020 19:30:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 16:09:32
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	25 Nov 2020 21:06:28
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:51:18

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:17
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:32:12
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	13 Dec 2020 19:30:42
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	13 Dec 2020 19:30:42
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	13 Dec 2020 19:30:25
DataPoint Un-verified.	Afifah Ayub (b) (4)	13 Dec 2020 19:30:25
	(b) (4)	
User entered '30 Nov 2020' reason for change: Data Entry Error	Afifah Ayub (b) (4)	13 Dec 2020 19:30:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 16:09:34
User entered empty.	Afifah Ayub (b) (4)	25 Nov 2020 21:06:28
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:51:18

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:17
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 16:09:36
User entered empty.	Afifah Ayub (b) (4)	25 Nov 2020 21:06:28
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:51:18

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:17
User entered empty.	System	25 Nov 2020 21:06:28

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:51:18

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:17
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 16:09:38
User entered 'Grade 3/Severe (Grade 3/Severe)'	Afifah Ayub (b) (4)	25 Nov 2020 21:06:28
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:51:18

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:17
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 16:09:42
User entered 'No (N)'	Afifah Ayub (b) (4)	25 Nov 2020 21:06:28
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:51:18

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:17
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 16:09:44
User entered '0'	Afifah Ayub (b) (4)	25 Nov 2020 21:06:28
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:51:18

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:17
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 16:09:46
User entered '0'	Afifah Ayub (b) (4)	25 Nov 2020 21:06:28
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:51:18

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:17
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 16:09:47
User entered '0'	Afifah Ayub (b) (4)	25 Nov 2020 21:06:28
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:51:18

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:17
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 16:09:49
User entered empty.	Afifah Ayub (b) (4)	25 Nov 2020 21:06:28
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:51:18

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:17
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 16:09:52
User entered empty.	Afifah Ayub (b) (4)	25 Nov 2020 21:06:28
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:51:18

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:17
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 16:09:54
User entered empty.	Afifah Ayub (b) (4)	25 Nov 2020 21:06:28
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:51:18

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:17
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 16:09:55
User entered empty.	Afifah Ayub (b) (4)	25 Nov 2020 21:06:28
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:51:18

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:17
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 16:09:57
User entered '0'	Afifah Ayub (b) (4)	25 Nov 2020 21:06:28
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:51:18

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:17
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 16:09:59
User entered '0'	Afifah Ayub (b) (4)	25 Nov 2020 21:06:28
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:51:18

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:17
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 16:10:02
User entered '0'	Afifah Ayub (b) (4)	25 Nov 2020 21:06:28
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:51:18

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:17
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 16:10:07
User entered 'Not Related (NOT RELATED)'	Afifah Ayub (b) (4)	25 Nov 2020 21:06:28
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:51:18

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:17
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:33:05
User entered 'Not Related (NOT RELATED)'	Afifah Ayub (b) (4)	25 Nov 2020 21:06:28
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:51:18

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:17
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 16:10:13
User entered 'Not Applicable (NOT APPLICABLE)'	Afifah Ayub (b) (4)	25 Nov 2020 21:06:28
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:51:18

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 06:16:15
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Un-verified.	Reagan Reed (b) (4)	02 Feb 2021 16:29:48
User entered '1' reason for change: Data Entry Error	(b) (4)	02 Feb 2021 16:29:48
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 16:10:16
User entered '0'	Afifah Ayub (b) (4)	25 Nov 2020 21:06:28

US3212394

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:51:18

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:17
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 16:10:18
User entered '0'	Afifah Ayub (b) (4)	25 Nov 2020 21:06:28
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:51:18

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 06:16:19
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User closed query 'Per DM CLR: Other Action Taken = Concomitant Procedure, however there is no Concomitant Procedure or Non-Drug Therapy 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 Feb 2021 11:55:51
Query 'Per DM CLR: Other Action Taken = Concomitant Procedure, however there is no Concomitant Procedure or Non-Drug Therapy 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).	Reagan Reed (b) (4)	02 Feb 2021 16:30:09
DataPoint Un-verified.	(b) (4)	02 Feb 2021 16:29:48
User entered '0' reason for change: Data Entry Error	Reagan Reed (b) (4)	02 Feb 2021 16:29:48
User opened query 'Per DM CLR: Other Action Taken = Concomitant Procedure, however there is no Concomitant Procedure or Non-Drug Therapy 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)	02 Feb 2021 16:00:44
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 16:10:19
User entered '1'	Afifah Ayub (b) (4)	25 Nov 2020 21:06:28

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:51:18

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:17
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:33:09
DataPoint Un-verified.	Afifah Ayub (b) (4)	13 Dec 2020 19:30:42
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Afifah Ayub (b) (4)	13 Dec 2020 19:30:42
Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 16:10:21
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Afifah Ayub (b) (4)	25 Nov 2020 21:06:28
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:51:18

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:17
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 16:10:23
User entered empty.	Afifah Ayub (b) (4)	25 Nov 2020 21:06:28
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:51:18

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:17
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 16:10:27
User entered empty.	Afifah Ayub (b) (4)	25 Nov 2020 21:06:28
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:51:18

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:17
User entered '0'	System	25 Nov 2020 21:06:28

US3212394

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:51:18

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:17
User entered '1'	System	25 Nov 2020 21:06:28

US3212394

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:51:18

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:17

US3212394

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:51:18

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:23

US3212394

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:51:18

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:23
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User closed query 'Per source, subject experienced 'headache'. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	31 Dec 2020 19:16:44
Query 'Per source, subject experienced 'headache'. Please verify and update accordingly.' answered with 'entered' (Site from CRA).	Reagan Reed (b) (4)	09 Dec 2020 19:53:13
	(b) (4)	
User opened query 'Per source, subject experienced 'headache'. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	08 Dec 2020 16:24:31
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 16:15:32
User coded data point as SOC: General disorders and administration site conditions, HLT: General system disorders NEC, HLT: Asthenic conditions, PT: Fatigue, LLT: Fatigue - version MedDRA\23.0.	Coder Import (b) (4)	25 Nov 2020 21:08:16
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	25 Nov 2020 21:08:16
	(b) (4)	
Data point term sent to Coder	System	25 Nov 2020 21:07:55
User entered 'fatigue'	Afifah Ayub (b) (4)	25 Nov 2020 21:07:07
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:51:18

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:23
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 16:15:38
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	25 Nov 2020 21:07:07
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:51:18

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:23
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:33:34
User entered 'No (N)'	Afifah Ayub (b) (4)	25 Nov 2020 21:07:07
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:51:18

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:23
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 16:15:44
User entered 'No (N)'	Afifah Ayub (b) (4)	25 Nov 2020 21:07:07
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:51:18

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:23
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 16:15:46
User entered '12 Nov 2020'	Afifah Ayub (b) (4)	25 Nov 2020 21:07:07
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:51:18

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:23
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 16:15:47
User entered empty.	Afifah Ayub (b) (4)	25 Nov 2020 21:07:07
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:51:18

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:23
User entered empty.	System	25 Nov 2020 21:07:07

US3212394

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:51:18

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:23
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:33:45
DataPoint Un-verified.	Afifah Ayub (b) (4)	13 Dec 2020 19:31:02
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	13 Dec 2020 19:31:02
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 16:15:50
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	25 Nov 2020 21:07:07
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:51:18

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:23
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:33:51
DataPoint Un-verified.	Afifah Ayub (b) (4)	13 Dec 2020 19:31:02
	(b) (4)	
User entered '30 Nov 2020' reason for change: Data Entry Error	Afifah Ayub (b) (4)	13 Dec 2020 19:31:02
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 16:15:52
User entered empty.	Afifah Ayub (b) (4)	25 Nov 2020 21:07:07
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:51:18

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:23
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 16:15:54
User entered empty.	Afifah Ayub (b) (4)	25 Nov 2020 21:07:07
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:51:18

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:23
User entered empty.	System	25 Nov 2020 21:07:07

US3212394

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:51:18

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:23
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 16:15:57
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Afifah Ayub (b) (4)	25 Nov 2020 21:07:07
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:51:18

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:23
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 16:15:58
User entered 'No (N)'	Afifah Ayub (b) (4)	25 Nov 2020 21:07:07
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:51:18

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:23
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 16:16:01
User entered '0'	Afifah Ayub (b) (4)	25 Nov 2020 21:07:07
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:51:18

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:23
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 16:16:03
User entered '0'	Afifah Ayub (b) (4)	25 Nov 2020 21:07:07
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:51:18

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:23
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 16:16:04
User entered '0'	Afifah Ayub (b) (4)	25 Nov 2020 21:07:07
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:51:18

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:23
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 16:16:06
User entered empty.	Afifah Ayub (b) (4)	25 Nov 2020 21:07:07
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:51:18

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:23
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 16:16:07
User entered empty.	Afifah Ayub (b) (4)	25 Nov 2020 21:07:07
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:51:18

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:23
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 16:16:10
User entered empty.	Afifah Ayub (b) (4)	25 Nov 2020 21:07:07
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:51:18

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:23
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 16:16:12
User entered empty.	Afifah Ayub (b) (4)	25 Nov 2020 21:07:07
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:51:18

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:23
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 16:16:13
User entered '0'	Afifah Ayub (b) (4)	25 Nov 2020 21:07:07
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:51:18

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:23
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 16:16:15
User entered '0'	Afifah Ayub (b) (4)	25 Nov 2020 21:07:07
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:51:18

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:23
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 16:16:17
User entered '0'	Afifah Ayub (b) (4)	25 Nov 2020 21:07:07
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:51:18

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:23
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 16:21:49
User entered 'Not Related (NOT RELATED)'	Afifah Ayub (b) (4)	25 Nov 2020 21:07:07
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:51:18

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:23
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:34:00
User entered 'Not Related (NOT RELATED)'	Afifah Ayub (b) (4)	25 Nov 2020 21:07:07
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:51:18

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:23
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 16:21:52
User entered 'Not Applicable (NOT APPLICABLE)'	Afifah Ayub (b) (4)	25 Nov 2020 21:07:07
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:51:18

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:23
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 16:21:55
User entered 'I'	Afifah Ayub (b) (4)	25 Nov 2020 21:07:07
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:51:18

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:23
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 16:22:01
User entered '0'	Afifah Ayub (b) (4)	25 Nov 2020 21:07:07
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:51:18

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:23
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 16:22:03
User entered '0'	Afifah Ayub (b) (4)	25 Nov 2020 21:07:07
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:51:18

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:23
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User closed query 'Per source, outcome is recovering/resolving. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	23 Dec 2020 22:34:08
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:34:06
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Afifah Ayub (b) (4)	13 Dec 2020 19:31:02
Data Entry Error	(b) (4)	
Query 'Per source, outcome is recovering/resolving. Please verify and update accordingly.' answered with 'updated' (Site from CRA).	Reagan Reed (b) (4)	09 Dec 2020 19:51:56
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change:	Reagan Reed (b) (4)	09 Dec 2020 19:51:51
Data Entry Error	(b) (4)	
User opened query 'Per source, outcome is recovering/resolving. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	08 Dec 2020 16:22:51
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Afifah Ayub (b) (4)	25 Nov 2020 21:07:07
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:51:18

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:23
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 16:23:08
User entered empty.	Afifah Ayub (b) (4)	25 Nov 2020 21:07:07
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:51:18

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:23
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 16:23:12
User entered empty.	Afifah Ayub (b) (4)	25 Nov 2020 21:07:07
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:51:18

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:23
User entered '0'	System	25 Nov 2020 21:07:07

US3212394

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:51:18

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:23
User entered '1'	System	25 Nov 2020 21:07:07

US3212394

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:51:18

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:23

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:51:18

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:29

US3212394

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:51:18

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:34:53
User coded data point as SOC: Nervous system disorders, HLG: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Headache - version MedDRA\\23.0.	Coder Import (b) (4)	09 Dec 2020 19:54:59
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	09 Dec 2020 19:54:59
	(b) (4)	
Data point term sent to Coder	System	09 Dec 2020 19:53:57
User entered 'Headache'	Reagan Reed (b) (4)	09 Dec 2020 19:53:01
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:51:18

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:35:00
User entered 'Yes (Y)'	Reagan Reed (b) (4)	09 Dec 2020 19:53:01
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:51:18

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:35:12
User entered 'No (N)'	Reagan Reed (b) (4)	09 Dec 2020 19:53:01
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:51:18

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:35:13
User entered 'No (N)'	Reagan Reed (b) (4)	09 Dec 2020 19:53:01
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:51:18

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:35:17
User entered '13 Nov 2020'	Reagan Reed (b) (4)	09 Dec 2020 19:53:01
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:51:18

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:35:18
User entered empty.	Reagan Reed (b) (4)	09 Dec 2020 19:53:01
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:51:18

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:29
User entered empty.	System	09 Dec 2020 19:53:01

US3212394

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:51:18

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:35:19
User entered 'No (N)'	Reagan Reed (b) (4)	09 Dec 2020 19:53:01
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:51:18

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:35:21
User entered '23 Nov 2020'	Reagan Reed (b) (4)	09 Dec 2020 19:53:01
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:51:18

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:35:23
User entered empty.	Reagan Reed (b) (4)	09 Dec 2020 19:53:01
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:51:18

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:29
User entered empty.	System	09 Dec 2020 19:53:01

US3212394

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:51:18

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:35:25
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Reagan Reed (b) (4)	09 Dec 2020 19:53:01
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:51:18

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:35:28
User entered 'No (N)'	Reagan Reed (b) (4)	09 Dec 2020 19:53:01
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:51:18

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:35:30
User entered '0'	Reagan Reed (b) (4)	09 Dec 2020 19:53:01
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:51:18

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:35:31
User entered '0'	Reagan Reed (b) (4)	09 Dec 2020 19:53:01
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:51:18

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:35:33
User entered '0'	Reagan Reed (b) (4)	09 Dec 2020 19:53:01
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:51:18

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:35:34
User entered empty.	Reagan Reed (b) (4)	09 Dec 2020 19:53:01
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:51:18

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:35:35
User entered empty.	Reagan Reed (b) (4)	09 Dec 2020 19:53:01
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:51:18

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:35:37
User entered empty.	Reagan Reed (b) (4)	09 Dec 2020 19:53:01
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:51:18

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:35:38
User entered empty.	Reagan Reed (b) (4)	09 Dec 2020 19:53:01
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:51:18

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:35:40
User entered '0'	Reagan Reed (b) (4)	09 Dec 2020 19:53:01
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:51:18

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:35:41
User entered '0'	Reagan Reed (b) (4)	09 Dec 2020 19:53:01
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:51:18

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:35:43
User entered '0'	Reagan Reed (b) (4)	09 Dec 2020 19:53:01
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:51:18

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:35:46
User entered 'Not Related (NOT RELATED)'	Reagan Reed (b) (4)	09 Dec 2020 19:53:01
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:51:18

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:35:48
User entered 'Not Related (NOT RELATED)'	Reagan Reed (b) (4)	09 Dec 2020 19:53:01
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:51:18

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:35:50
User entered 'None (NONE)'	Reagan Reed (b) (4)	09 Dec 2020 19:53:01
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:51:18

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:35:51
User entered 'I'	Reagan Reed (b) (4)	09 Dec 2020 19:53:01
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:51:18

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:35:53
User entered '0'	Reagan Reed (b) (4)	09 Dec 2020 19:53:01
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:51:18

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:35:54
User entered '0'	Reagan Reed (b) (4)	09 Dec 2020 19:53:01
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:51:18

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:35:55
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Reagan Reed (b) (4) (b) (4)	09 Dec 2020 19:53:01

US3212394

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:51:18

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:35:57
User entered empty.	Reagan Reed (b) (4)	09 Dec 2020 19:53:01
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:51:18

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:35:59
User entered empty.	Reagan Reed (b) (4)	09 Dec 2020 19:53:01
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:51:18

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:29
User entered '0'	System	09 Dec 2020 19:53:01

(b)

US3212394

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:51:18

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:29
User entered '1'	System	09 Dec 2020 19:53:01

US3212394

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:51:18

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:29

US3212394

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:51:18

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:37

US3212394

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:51:18

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:37
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:36:14
User coded data point as SOC: Gastrointestinal disorders, HLG: Gastrointestinal signs and symptoms, HLT: Faecal abnormalities NEC, PT: Faeces discoloured, LLT: Stool black - version MedDRA\\23.0.	Coder Import (b) (4)	09 Dec 2020 22:59:46
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	09 Dec 2020 22:59:46
	(b) (4)	
Data point term sent to Coder	System	09 Dec 2020 20:05:24
User entered 'Black Stool'	Reagan Reed (b) (4)	09 Dec 2020 20:05:04
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:51:18

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:37
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:36:16
User entered 'No (N)'	Reagan Reed (b) (4)	09 Dec 2020 20:05:04
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:51:18

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:37
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:36:19
User entered 'No (N)'	Reagan Reed (b) (4)	09 Dec 2020 20:05:04
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:51:18

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:37
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:36:21
User entered 'No (N)'	Reagan Reed (b) (4)	09 Dec 2020 20:05:04
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:51:18

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:37
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:36:24
User entered '12 Nov 2020'	Reagan Reed (b) (4)	09 Dec 2020 20:05:04
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:51:18

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:37
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:36:26
User entered empty.	Reagan Reed (b) (4)	09 Dec 2020 20:05:04
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:51:18

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:37
User entered empty.	System	09 Dec 2020 20:05:04

US3212394

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:51:18

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:37
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:36:28
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Dec 2020 20:05:10
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Dec 2020 20:05:10
User entered 'No (N)' reason for change: Data Entry Error	Reagan Reed (b) (4)	09 Dec 2020 20:05:10
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Dec 2020 20:05:04
User entered empty.	Reagan Reed (b) (4)	09 Dec 2020 20:05:04
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:51:18

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:37
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:36:29
User entered '19 Nov 2020'	Reagan Reed (b) (4)	09 Dec 2020 20:05:04
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:51:18

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:37
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:36:31
User entered empty.	Reagan Reed (b) (4)	09 Dec 2020 20:05:04
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:51:18

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:37
User entered empty.	System	09 Dec 2020 20:05:04

US3212394

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:51:18

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:37
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:36:32
User entered 'Grade 1/Mild (Grade 1/Mild)'	Reagan Reed (b) (4)	09 Dec 2020 20:05:04
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:51:18

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:37
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:36:34
User entered 'No (N)'	Reagan Reed (b) (4)	09 Dec 2020 20:05:04
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:51:18

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:37
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:36:36
User entered '0'	Reagan Reed (b) (4)	09 Dec 2020 20:05:04
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:51:18

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:37
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:36:38
User entered '0'	Reagan Reed (b) (4)	09 Dec 2020 20:05:04
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:51:18

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:37
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:36:41
User entered '0'	Reagan Reed (b) (4)	09 Dec 2020 20:05:04
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:51:18

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:37
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:36:42
User entered empty.	Reagan Reed (b) (4)	09 Dec 2020 20:05:04
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:51:18

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:37
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:36:44
User entered empty.	Reagan Reed (b) (4)	09 Dec 2020 20:05:04
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:51:18

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:37
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:36:45
User entered empty.	Reagan Reed (b) (4)	09 Dec 2020 20:05:04
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:51:18

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:37
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:36:47
User entered empty.	Reagan Reed (b) (4)	09 Dec 2020 20:05:04
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:51:18

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:37
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:36:48
User entered '0'	Reagan Reed (b) (4)	09 Dec 2020 20:05:04
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:51:18

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:37
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:36:50
User entered '0'	Reagan Reed (b) (4)	09 Dec 2020 20:05:04
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:51:18

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:37
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:36:52
User entered '0'	Reagan Reed (b) (4)	09 Dec 2020 20:05:04
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:51:18

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:37
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:36:56
User entered 'Not Related (NOT RELATED)'	Reagan Reed (b) (4)	09 Dec 2020 20:05:04
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:51:18

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:37
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:36:57
User entered 'Not Related (NOT RELATED)'	Reagan Reed (b) (4)	09 Dec 2020 20:05:04
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:51:18

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:37
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:36:59
User entered 'None (NONE)'	Reagan Reed (b) (4)	09 Dec 2020 20:05:04
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:51:18

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:37
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:37:03
User entered 'l'	Reagan Reed (b) (4)	09 Dec 2020 20:05:04
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:51:18

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:37
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:37:06
User entered '0'	Reagan Reed (b) (4)	09 Dec 2020 20:05:04
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:51:18

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:37
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:37:08
User entered '0'	Reagan Reed (b) (4)	09 Dec 2020 20:05:04
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:51:18

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:37
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:37:09
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Reagan Reed (b) (4)	09 Dec 2020 20:05:04
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:51:18

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:37
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:37:11
User entered empty.	Reagan Reed (b) (4)	09 Dec 2020 20:05:04
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:51:18

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:37
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:37:13
User entered empty.	Reagan Reed (b) (4)	09 Dec 2020 20:05:04
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:51:18

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:37
User entered '0'	System	09 Dec 2020 20:05:04

US3212394

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:51:18

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:37
User entered '0'	System	09 Dec 2020 20:05:04

US3212394

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:51:18

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:37

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:51:18

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:41

US3212394

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:51:18

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:41
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:38:14
User coded data point as SOC: Gastrointestinal disorders, HLG: Gastrointestinal signs and symptoms, HLT: Gastrointestinal signs and symptoms NEC, PT: Abdominal discomfort, LLT: Upset stomach - version MedDRA\\23.0.	Coder Import (b) (4)	09 Dec 2020 20:10:44
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	09 Dec 2020 20:10:44
	(b) (4)	
Data point term sent to Coder	System	09 Dec 2020 20:09:27
User entered 'upset stomach'	Reagan Reed (b) (4)	09 Dec 2020 20:09:21
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:51:18

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:41
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:38:16
User entered 'No (N)'	Reagan Reed (b) (4)	09 Dec 2020 20:09:21
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:51:18

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:41
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 22:08:18
User entered 'No (N)'	Reagan Reed (b) (4)	09 Dec 2020 20:09:21
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:51:18

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:41
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:38:22
User entered 'No (N)'	Reagan Reed (b) (4)	09 Dec 2020 20:09:21
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:51:18

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:41
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:38:23
User entered '13 Nov 2020'	Reagan Reed (b) (4)	09 Dec 2020 20:09:21
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:51:18

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:41
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:38:25
User entered empty.	Reagan Reed (b) (4)	09 Dec 2020 20:09:21
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:51:18

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:41
User entered empty.	System	09 Dec 2020 20:09:21

US3212394

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:51:18

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:41
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:38:27
User entered 'No (N)'	Reagan Reed (b) (4)	09 Dec 2020 20:09:21
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:51:18

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:41
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:38:29
User entered '23 Nov 2020'	Reagan Reed (b) (4)	09 Dec 2020 20:09:21
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:51:18

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:41
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:38:31
User entered empty.	Reagan Reed (b) (4)	09 Dec 2020 20:09:21
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:51:18

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:41
User entered empty.	System	09 Dec 2020 20:09:21

US3212394

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:51:18

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:41
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:38:33
User entered 'Grade 1/Mild (Grade 1/Mild)'	Reagan Reed (b) (4)	09 Dec 2020 20:09:21
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:51:18

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:41
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:38:34
User entered 'No (N)'	Reagan Reed (b) (4)	09 Dec 2020 20:09:21
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:51:18

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:41
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:38:36
User entered '0'	Reagan Reed (b) (4)	09 Dec 2020 20:09:21
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:51:18

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:41
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:38:38
User entered '0'	Reagan Reed (b) (4)	09 Dec 2020 20:09:21
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:51:18

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:41
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:38:39
User entered '0'	Reagan Reed (b) (4)	09 Dec 2020 20:09:21
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:51:18

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:41
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:38:40
User entered empty.	Reagan Reed (b) (4)	09 Dec 2020 20:09:21
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:51:18

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:41
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:38:42
User entered empty.	Reagan Reed (b) (4)	09 Dec 2020 20:09:21
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:51:18

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:41
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:38:43
User entered empty.	Reagan Reed (b) (4)	09 Dec 2020 20:09:21
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:51:18

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:41
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:38:45
User entered empty.	Reagan Reed (b) (4)	09 Dec 2020 20:09:21
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:51:18

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:41
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:38:47
User entered '0'	Reagan Reed (b) (4)	09 Dec 2020 20:09:21
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:51:18

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:41
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:38:49
User entered '0'	Reagan Reed (b) (4)	09 Dec 2020 20:09:21
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:51:18

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:41
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:38:50
User entered '0'	Reagan Reed (b) (4)	09 Dec 2020 20:09:21
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:51:18

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:41
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:38:54
User entered 'Not Related (NOT RELATED)'	Reagan Reed (b) (4)	09 Dec 2020 20:09:21
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:51:18

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:41
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 22:08:25
User entered 'Not Related (NOT RELATED)'	Reagan Reed (b) (4)	09 Dec 2020 20:09:21
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:51:18

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:41
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:39:03
User entered 'None (NONE)'	Reagan Reed (b) (4)	09 Dec 2020 20:09:21
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:51:18

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:41
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:39:05
User entered 'I'	Reagan Reed (b) (4)	09 Dec 2020 20:09:21
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:51:18

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:41
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:39:07
User entered '0'	Reagan Reed (b) (4)	09 Dec 2020 20:09:21
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:51:18

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:41
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:39:08
User entered '0'	Reagan Reed (b) (4)	09 Dec 2020 20:09:21
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:51:18

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:41
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:39:10
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Reagan Reed (b) (4)	09 Dec 2020 20:09:21
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:51:18

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:41
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:39:11
User entered empty.	Reagan Reed (b) (4)	09 Dec 2020 20:09:21
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:51:18

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:41
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:39:13
User entered empty.	Reagan Reed (b) (4)	09 Dec 2020 20:09:21
	(b) (4)	

US3212394

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:51:18

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:41
User entered '0'	System	09 Dec 2020 20:09:21

US3212394

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:51:18

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:41
User entered '0'	System	09 Dec 2020 20:09:21

US3212394

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:51:18

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:39:41

US3212394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 15:51:18

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:28:43
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 16:39:57
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	14 Sep 2020 00:21:03

US3212394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:51:18

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 16:47:11
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)	14 Sep 2020 00:22:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Sep 2020 00:22:41
Data point term sent to Coder	System	14 Sep 2020 00:22:06
User entered 'Multivitamins'	Afifah Ayub (b) (4)	14 Sep 2020 00:21:40
	(b) (4)	

US3212394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:51:18

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 06:16:57
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User closed query 'Per source, answer is 'No' please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	31 Dec 2020 19:14:10
Query 'Per source, answer is 'No' please verify and update accordingly.' answered with 'updated' (Site from CRA).	Reagan Reed (b) (4)	09 Dec 2020 19:47:34
User opened query 'Per source, answer is 'No' please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	08 Dec 2020 16:47:59
User closed query 'Per CDM: Response is recorded as No; however, indication is recorded as health promotion measure. Please clarify if this was given as a prophylactic or preventative measure. If yes, please update accordingly' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 14:44:44
Query 'Per CDM: Response is recorded as No; however, indication is recorded as health promotion measure. Please clarify if this was given as a prophylactic or preventative measure. If yes, please update accordingly' answered with 'updated' (Site from DM).	Reagan Reed (b) (4)	19 Nov 2020 14:04:15
User entered 'Yes (Y)' reason for change: Data Entry Error	Reagan Reed (b) (4)	19 Nov 2020 14:04:05
User opened query 'Per CDM: Response is recorded as No; however, indication is recorded as health promotion measure. Please clarify if this was given as a prophylactic or preventative measure. If yes, please update accordingly' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 10:47:19
User entered 'No (N)'	Afifah Ayub (b) (4)	14 Sep 2020 00:21:40

US3212394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:51:18

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 16:48:02
User entered 'Dietary supplement'	Afifah Ayub (b) (4)	14 Sep 2020 00:21:40
	(b) (4)	

US3212394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:51:18

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 16:48:08
User entered 'I'	Afifah Ayub (b) (4)	14 Sep 2020 00:21:40
	(b) (4)	

US3212394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:51:18

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 16:48:10
User entered 'tablet (TABLET)'	Afifah Ayub (b) (4)	14 Sep 2020 00:21:40
	(b) (4)	

US3212394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:51:18

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 16:49:13
User entered empty.	Afifah Ayub (b) (4)	14 Sep 2020 00:21:40
	(b) (4)	

US3212394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:51:18

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 16:49:18
User entered 'once daily (QD)'	Afifah Ayub (b) (4)	14 Sep 2020 00:21:40
	(b) (4)	

US3212394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:51:18

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 16:49:19
User entered empty.	Afifah Ayub (b) (4)	14 Sep 2020 00:21:40
	(b) (4)	

US3212394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:51:18

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 16:49:22
User entered 'Oral (ORAL)'	Afifah Ayub (b) (4)	14 Sep 2020 00:21:40
	(b) (4)	

US3212394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:51:18

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 16:49:25
User entered empty.	Afifah Ayub (b) (4)	14 Sep 2020 00:21:40
	(b) (4)	

US3212394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:51:18

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 16:49:27
User entered 'UN UNK 1975'	Afifah Ayub (b) (4)	14 Sep 2020 00:21:40
	(b) (4)	

US3212394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:51:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 16:49:29
User entered '0'	Afifah Ayub (b) (4)	14 Sep 2020 00:21:40
	(b) (4)	

US3212394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:51:18

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 16:49:34
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	14 Sep 2020 00:21:40
	(b) (4)	

US3212394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:51:18

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 16:49:37
User entered empty.	Afifah Ayub (b) (4)	14 Sep 2020 00:21:40
	(b) (4)	

US3212394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:51:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 16:49:39
User entered 'No (N)'	Afifah Ayub (b) (4)	14 Sep 2020 00:21:40
	(b) (4)	

US3212394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:51:18

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Sep 2020 00:21:40

US3212394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:51:18

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Sep 2020 00:21:40

US3212394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:51:18

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Sep 2020 00:21:40

US3212394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:51:18

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:34:22
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 16:49:50
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Nov 2020 21:10:37
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Nov 2020 21:10:37
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Nov 2020 10:22:13
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Nov 2020 10:22:13
Data point term sent to Coder	System	02 Nov 2020 18:58:51
Coding entries removed.	Nirja Shah (b) (4)	02 Nov 2020 18:58:13
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Sep 2020 20:27:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Sep 2020 20:27:46
Data point term sent to Coder	System	15 Sep 2020 20:26:41
User entered 'tylenol (acetaminophen)'	Heather Leary (b) (4)	15 Sep 2020 20:25:48

US3212394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:51:18

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:34:22
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 16:49:53
User entered 'No (N)'	Heather Leary (b) (4)	15 Sep 2020 20:25:48

US3212394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:51:18

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:34:22
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 16:49:57
User entered 'Injection site pain' reason for change:	Nirja Shah (b) (4)	02 Nov 2020 18:58:13
Data Entry Error	(b) (4)	
User entered 'fever/pain reactogenicity'	Heather Leary (b) (4)	15 Sep 2020 20:25:48
	(b) (4)	

US3212394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:51:18

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:34:22
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 16:49:59
User entered '500'	Heather Leary (b) (4)	15 Sep 2020 20:25:48

US3212394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:51:18

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:34:22
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 16:50:05
DataPoint Un-verified.	(b) (4), (b) (6)	08 Dec 2020 16:50:02
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 16:50:01
User entered 'mg (mg)'	Heather Leary (b) (4)	15 Sep 2020 20:25:48
	(b) (4)	

US3212394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:51:18

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:34:22
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 16:50:04
User entered empty.	Heather Leary (b) (4)	15 Sep 2020 20:25:48

US3212394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:51:18

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:34:22
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 16:50:09
User entered 'once (ONCE)'	Heather Leary (b) (4)	15 Sep 2020 20:25:48

US3212394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:51:18

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:34:22
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 16:50:12
User entered empty.	Heather Leary (b) (4)	15 Sep 2020 20:25:48

US3212394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:51:18

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:34:22
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 16:50:14
User entered 'Oral (ORAL)'	Heather Leary (b) (4)	15 Sep 2020 20:25:48

US3212394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:51:18

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:34:22
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 16:50:16
User entered empty.	Heather Leary (b) (4)	15 Sep 2020 20:25:48

US3212394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:51:18

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:34:22
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 16:50:18
User entered '15 Sep 2020'	Heather Leary (b) (4)	15 Sep 2020 20:25:48

US3212394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:51:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:34:22
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 16:50:19
User entered '0'	Heather Leary (b) (4)	15 Sep 2020 20:25:48

US3212394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:51:18

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:34:22
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 16:50:21
User entered 'No (N)'	Heather Leary (b) (4)	15 Sep 2020 20:25:48

US3212394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:51:18

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:34:22
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 16:50:23
User entered '15 Sep 2020'	Heather Leary (b) (4)	15 Sep 2020 20:25:48

US3212394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:51:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:34:22
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 16:50:26
User entered 'Yes (Y)'	Heather Leary (b) (4)	15 Sep 2020 20:25:48

US3212394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:51:18

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:34:22
User entered empty.	System	15 Sep 2020 20:25:48

US3212394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:51:18

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:34:22
User entered empty.	System	15 Sep 2020 20:25:48

US3212394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:51:18

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:34:22
User entered empty.	System	15 Sep 2020 20:25:48

US3212394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:51:18

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:34:22
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 16:50:45
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: NAPROXEN SODIUM, PRODUCTSYNONYM: ALEVE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Nov 2020 10:22:13
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	
Data point term sent to Coder	System	02 Nov 2020 18:58:51
Coding entries removed.	Nirja Shah (b) (4)	02 Nov 2020 18:58:25
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: NAPROXEN SODIUM, PRODUCTSYNONYM: ALEVE - version WHODrug-Global-B3\\202003.	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Sep 2020 20:42:51
Data point term sent to Coder	System	15 Sep 2020 20:26:41
User entered 'aleve (naproxen)'	Heather Leary (b) (4)	15 Sep 2020 20:26:19

US3212394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:51:18

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:34:22
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 16:50:47
User entered 'No (N)'	Heather Leary (b) (4)	15 Sep 2020 20:26:19

US3212394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:51:18

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:34:22
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 16:50:49
User entered 'Injection site pain' reason for change:	Nirja Shah (b) (4)	02 Nov 2020 18:58:25
Data Entry Error	(b) (4)	
User entered 'fever/pain reactogenicity'	Heather Leary (b) (4)	15 Sep 2020 20:26:19

US3212394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:51:18

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:34:22
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 16:50:51
User entered '440'	Heather Leary (b) (4)	15 Sep 2020 20:26:19

US3212394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:51:18

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:34:22
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 16:50:56
User entered 'mg (mg)'	Heather Leary (b) (4)	15 Sep 2020 20:26:19

US3212394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:51:18

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:34:22
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 16:50:53
User entered empty.	Heather Leary (b) (4)	15 Sep 2020 20:26:19

US3212394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:51:18

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:34:22
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 16:50:57
User entered 'once (ONCE)'	Heather Leary (b) (4)	15 Sep 2020 20:26:19

US3212394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:51:18

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:34:22
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 16:51:00
User entered empty.	Heather Leary (b) (4)	15 Sep 2020 20:26:19

US3212394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:51:18

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:34:22
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 16:51:02
User entered 'Oral (ORAL)'	Heather Leary (b) (4)	15 Sep 2020 20:26:19

US3212394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:51:18

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:34:22
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 16:51:06
User entered empty.	Heather Leary (b) (4)	15 Sep 2020 20:26:19

US3212394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:51:18

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:34:22
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 16:51:09
User entered '15 Sep 2020'	Heather Leary (b) (4)	15 Sep 2020 20:26:19

US3212394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:51:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:34:22
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 16:51:11
User entered '0'	Heather Leary (b) (4)	15 Sep 2020 20:26:19

US3212394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:51:18

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:34:22
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 16:51:18
User entered 'No (N)'	Heather Leary (b) (4)	15 Sep 2020 20:26:19

US3212394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:51:18

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:34:22
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 16:51:22
User entered '15 Sep 2020'	Heather Leary (b) (4)	15 Sep 2020 20:26:19

US3212394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:51:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:34:22
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 16:51:25
User entered 'Yes (Y)'	Heather Leary (b) (4)	15 Sep 2020 20:26:19

US3212394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:51:18

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:34:22
User entered empty.	System	15 Sep 2020 20:26:19

US3212394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:51:18

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:34:22
User entered empty.	System	15 Sep 2020 20:26:19

US3212394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:51:18

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:34:22
User entered empty.	System	15 Sep 2020 20:26:19

US3212394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:51:18

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:34:25
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 16:51:39
DataPoint Un-verified.	(b) (4), (b) (6)	08 Dec 2020 16:51:37
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 16:51:36
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: PENICILLINS WITH EXTENDED SPECTRUM, PRODUCT: AMOXICILLIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Nov 2020 03:46:40
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Nov 2020 03:46:40
Data point term sent to Coder	System	13 Nov 2020 21:48:46
User entered 'Amoxicillin'	Laura Ngansop Djampou (b) (4)	13 Nov 2020 21:48:00

US3212394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:51:18

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:34:25
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 16:51:40
User entered 'No (N)'	Laura Ngansop Djampou (b) (4)	13 Nov 2020 21:48:00

US3212394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:51:18

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:34:25
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User closed query 'Per DM CLR: This Conmed is given for the AE#04. It seems that "Other Action Taken" on the AE eCRF does not reflect that a CM was given. Please review and reconcile CM and AE eCRF as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	18 Dec 2020 10:33:59
Query 'Per DM CLR: This Conmed is given for the AE#04. It seems that "Other Action Taken" on the AE eCRF does not reflect that a CM was given. Please review and reconcile CM and AE eCRF as appropriate. Otherwise, provide clarification.' answered with 'updated' (Site from DM).	Reagan Reed (b) (4)	09 Dec 2020 19:47:54
User opened query 'Per DM CLR: This Conmed is given for the AE#04. It seems that "Other Action Taken" on the AE eCRF does not reflect that a CM was given. Please review and reconcile CM and AE eCRF as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	09 Dec 2020 14:26:40
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 16:53:43
User entered 'Otitis'	Laura Ngansop Djampou (b) (4)	13 Nov 2020 21:48:00

US3212394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:51:18

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:34:25
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 16:53:48
User entered '250'	Laura Ngansop Djampou (b) (4)	13 Nov 2020 21:48:00

US3212394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:51:18

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:34:25
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 16:53:50
User entered 'mg (mg)'	Laura Ngansop Djampou (b) (4)	13 Nov 2020 21:48:00

US3212394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:51:18

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:34:25
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 16:53:52
User entered empty.	Laura Ngansop Djampou (b) (4)	13 Nov 2020 21:48:00

US3212394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:51:18

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:34:25
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 16:53:56
User entered 'once daily (QD)'	Laura Ngansop Djampou (b) (4)	13 Nov 2020 21:48:00

US3212394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:51:18

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:34:25
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 16:54:40
User entered empty.	Laura Ngansop Djampou (b) (4)	13 Nov 2020 21:48:00

US3212394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:51:18

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:34:25
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 16:54:42
User entered 'Oral (ORAL)'	Laura Ngansop Djampou (b) (4)	13 Nov 2020 21:48:00

US3212394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:51:18

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:34:25
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 16:54:44
User entered empty.	Laura Ngansop Djampou (b) (4)	13 Nov 2020 21:48:00

US3212394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:51:18

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:34:25
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 16:54:47
User entered '04 Nov 2020' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	07 Dec 2020 20:13:42
User entered '4 Nov 2020'	Laura Ngansop Djampou (b) (4)	13 Nov 2020 21:48:00

US3212394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:51:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:34:25
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 16:54:49
User entered '0'	Laura Ngansop Djampou (b) (4)	13 Nov 2020 21:48:00

US3212394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:51:18

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:34:25
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 16:54:54
User entered 'No (N)'	Laura Ngansop Djampou (b) (4)	13 Nov 2020 21:48:00

US3212394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:51:18

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:34:25
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 16:54:57
User entered '13 Nov 2020'	Laura Ngansop Djampou (b) (4)	13 Nov 2020 21:48:00

US3212394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:51:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:34:25
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 16:55:02
User entered 'No (N)'	Laura Ngansop Djampou (b) (4)	13 Nov 2020 21:48:00

US3212394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:51:18

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:34:25
User entered '1'	System	13 Nov 2020 21:48:00

US3212394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:51:18

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:34:25
User entered '1'	System	13 Nov 2020 21:48:00

US3212394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:51:18

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:34:25
User entered '804 (804)'	System	13 Nov 2020 21:48:00

US3212394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:51:18

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:34:27
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 16:55:19
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: QUINOLONE ANTIBACTERIALS, ATC: FLUOROQUINOLONES, PRODUCT: LEVOFLOXACIN, PRODUCTSYNONYM: LEVAQUIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Nov 2020 07:26:10
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Nov 2020 07:26:10
Data point term sent to Coder	System	25 Nov 2020 21:34:24
Data point term sent to Coder	System	25 Nov 2020 21:10:57
User entered 'Levaquin'	Reagan Reed (b) (4)	25 Nov 2020 21:10:23

US3212394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:51:18

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:34:27
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 16:55:21
User entered 'No (N)'	Reagan Reed (b) (4)	25 Nov 2020 21:10:23

US3212394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:51:18

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:34:27
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 16:56:37
User entered 'Dyspnea' reason for change: Data Entry Error	Reagan Reed (b) (4)	25 Nov 2020 21:33:38
User entered 'Shortness of Breath'	Reagan Reed (b) (4)	25 Nov 2020 21:10:23

US3212394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:51:18

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:34:27
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 16:56:59
User entered '500'	Reagan Reed (b) (4)	25 Nov 2020 21:10:23

US3212394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:51:18

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:34:27
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 16:57:02
User entered 'mg (mg)'	Reagan Reed (b) (4)	25 Nov 2020 21:10:23

US3212394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:51:18

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:34:27
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 16:57:04
User entered empty.	Reagan Reed (b) (4)	25 Nov 2020 21:10:23

US3212394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:51:18

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:34:27
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 16:57:08
User entered 'once daily (QD)'	Reagan Reed (b) (4)	25 Nov 2020 21:10:23

US3212394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:51:18

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:34:27
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 16:57:10
User entered empty.	Reagan Reed (b) (4)	25 Nov 2020 21:10:23

US3212394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:51:18

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:34:27
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 16:57:12
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Reagan Reed (b) (4)	25 Nov 2020 21:10:23

US3212394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:51:18

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:34:27
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 16:57:14
User entered empty.	Reagan Reed (b) (4)	25 Nov 2020 21:10:23

US3212394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:51:18

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:34:27
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 16:57:16
User entered '21 Nov 2020'	Reagan Reed (b) (4)	25 Nov 2020 21:10:23

US3212394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:51:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:34:27
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 16:57:19
User entered '0'	Reagan Reed (b) (4)	25 Nov 2020 21:10:23

US3212394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:51:18

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:34:27
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 16:57:20
User entered 'No (N)'	Reagan Reed (b) (4)	25 Nov 2020 21:10:23

US3212394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:51:18

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:34:27
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 16:57:22
User entered '22 Nov 2020'	Reagan Reed (b) (4)	25 Nov 2020 21:10:23

US3212394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:51:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:34:27
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 16:57:24
User entered 'No (N)'	Reagan Reed (b) (4)	25 Nov 2020 21:10:23

US3212394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:51:18

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:34:27
User entered '1'	System	25 Nov 2020 21:10:23

US3212394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:51:18

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:34:27
User entered '1'	System	25 Nov 2020 21:10:23

US3212394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:51:18

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:34:27
User entered '804 (804)'	System	25 Nov 2020 21:10:23

US3212394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:51:18

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:34:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 16:58:40
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, ATC: MACROLIDES, PRODUCT: AZITHROMYCIN, PRODUCTSYNONYM: ZITHROMAX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Nov 2020 23:17:07
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Nov 2020 23:17:07
Data point term sent to Coder	System	25 Nov 2020 21:33:21
Data point term sent to Coder	System	25 Nov 2020 21:11:58
User entered 'Zithromax'	Reagan Reed (b) (4)	25 Nov 2020 21:11:43

US3212394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:51:18

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:34:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 16:58:42
User entered 'No (N)'	Reagan Reed (b) (4)	25 Nov 2020 21:11:43

US3212394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:51:18

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:34:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 16:58:45
User entered 'Dyspnea' reason for change: Data Entry Error	Reagan Reed (b) (4)	25 Nov 2020 21:33:19
User entered 'shortness of breath'	Reagan Reed (b) (4)	25 Nov 2020 21:11:43

US3212394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:51:18

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:34:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User closed query 'Per DM CLR: Please review the dose recorded as this is not the usual dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM). Query 'Per DM CLR: Please review the dose recorded as this is not the usual dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' answered with 'correct entry per subject' (Site from DM).	(b) (4), (b) (6)	10 Mar 2021 10:13:02
User opened query 'Per DM CLR: Please review the dose recorded as this is not the usual dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM). DataPoint Verified.	Reagan Reed (b) (4)	09 Mar 2021 14:07:24
User entered '1000'	(b) (4), (b) (6)	09 Mar 2021 06:50:57
	(b) (4), (b) (6)	08 Dec 2020 16:58:48
	Reagan Reed (b) (4)	25 Nov 2020 21:11:43

US3212394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:51:18

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:34:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 16:58:49
User entered 'mg (mg)'	Reagan Reed (b) (4)	25 Nov 2020 21:11:43

US3212394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:51:18

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:34:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 16:58:51
User entered empty.	Reagan Reed (b) (4)	25 Nov 2020 21:11:43

US3212394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:51:18

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:34:29
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 06:17:14
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User closed query ""Per DM CLR: Please review frequency as this was not given once per ongoing dates. Either update frequency or provide end date. Else, clarify. "	(b) (4), (b) (6)	26 Jan 2021 18:41:46
' (Site from DM). Query ""Per DM CLR: Please review frequency as this was not given once per ongoing dates. Either update frequency or provide end date. Else, clarify. "	Heather Leary (b) (4) (b) (4)	22 Jan 2021 15:56:27
' answered with 'updated' (Site from DM). DataPoint Un-verified.	Heather Leary (b) (4) (b) (4)	22 Jan 2021 15:56:17
User entered 'once daily (QD)' reason for change: Data Entry Error	Heather Leary (b) (4) (b) (4)	22 Jan 2021 15:56:17
User opened query ""Per DM CLR: Please review frequency as this was not given once per ongoing dates. Either update frequency or provide end date. Else, clarify. "	(b) (4), (b) (6)	22 Jan 2021 03:28:13
' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 16:58:53
User entered 'once (ONCE)'	Reagan Reed (b) (4) (b) (4)	25 Nov 2020 21:11:43

US3212394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:51:18

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:34:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 16:58:56
User entered empty.	Reagan Reed (b) (4)	25 Nov 2020 21:11:43

US3212394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:51:18

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:34:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 16:58:57
User entered 'Oral (ORAL)'	Reagan Reed (b) (4)	25 Nov 2020 21:11:43

US3212394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:51:18

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:34:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 16:58:59
User entered empty.	Reagan Reed (b) (4)	25 Nov 2020 21:11:43

US3212394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:51:18

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:34:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 16:59:01
User entered '25 Nov 2020'	Reagan Reed (b) (4)	25 Nov 2020 21:11:43

US3212394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:51:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:34:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 16:59:02
User entered '0'	Reagan Reed (b) (4)	25 Nov 2020 21:11:43

US3212394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:51:18

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:34:29
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 06:17:17
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Un-verified.	Heather Leary (b) (4)	22 Jan 2021 15:56:17
User entered 'No (N)' reason for change: Data Entry Error	Heather Leary (b) (4)	22 Jan 2021 15:56:17
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 16:59:04
User entered 'Yes (Y)'	Reagan Reed (b) (4)	25 Nov 2020 21:11:43

US3212394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:51:18

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:34:29
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 06:17:19
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Un-verified.	Heather Leary (b) (4)	22 Jan 2021 15:56:17
User entered '30 Nov 2020' reason for change: Data Entry Error	Heather Leary (b) (4)	22 Jan 2021 15:56:17
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 16:59:06
User entered empty.	Reagan Reed (b) (4)	25 Nov 2020 21:11:43

US3212394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:51:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:34:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 16:59:08
User entered 'No (N)'	Reagan Reed (b) (4)	25 Nov 2020 21:11:43

US3212394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:51:18

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:34:29
User entered '1'	System	22 Jan 2021 15:56:17
User entered empty.	System	25 Nov 2020 21:11:43

US3212394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:51:18

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:34:29
User entered '1'	System	22 Jan 2021 15:56:17
User entered empty.	System	25 Nov 2020 21:11:43

US3212394

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:51:18

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:34:29
User entered '804 (804)'	System	22 Jan 2021 15:56:17
User entered empty.	System	25 Nov 2020 21:11:43

US3212394

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 15:51:18

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:28:43
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 06:17:31
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Un-verified.	Reagan Reed (b) (4)	02 Feb 2021 16:26:39
User entered 'Yes (Y)' reason for change: Data Entry Error	Reagan Reed (b) (4)	02 Feb 2021 16:26:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 16:25:54
User entered 'No (N)'	Afifah Ayub (b) (4)	14 Sep 2020 00:18:51

US3212394

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:51:18

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 06:17:43
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered '19 Nov 2020'	Reagan Reed (b) (4)	02 Feb 2021 16:26:56

US3212394

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:51:18

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 06:17:43
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'Chest CT'	Reagan Reed (b) (4)	02 Feb 2021 16:26:56

US3212394

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:51:18

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 06:17:43
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'Adverse Event (AE)'	Reagan Reed (b) (4)	02 Feb 2021 16:26:56

US3212394

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:51:18

[If indication is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 06:17:43
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered empty.	Reagan Reed (b) (4)	02 Feb 2021 16:26:56

US3212394

Folder: SAE USA-US115-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:51:18

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 15:33:50
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:03:46
User entered	System	30 Nov 2020 16:03:01
'USA-US115-2020-MRNA-1273-P301000014'		

US3212394

Folder: SAE USA-US115-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:51:18

Serious

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 15:33:50
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:03:46
User entered 'Yes (Y)'	System	30 Nov 2020 16:03:01

US3212394

Folder: SAE USA-US115-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:51:18

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 15:33:50
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:03:46
User entered 'No (N)'	System	30 Nov 2020 16:03:01

US3212394

Folder: SAE USA-US115-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:51:18

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 15:33:50
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:03:46
User entered 'No (N)'	System	30 Nov 2020 16:03:01

US3212394

Folder: SAE USA-US115-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:51:18

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 15:33:50
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:03:46
User entered 'Yes (Y)'	System	30 Nov 2020 16:03:01

US3212394

Folder: SAE USA-US115-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:51:18

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 15:33:50
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:03:46
User entered 'No (N)'	System	30 Nov 2020 16:03:01

US3212394

Folder: SAE USA-US115-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:51:18

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 15:33:50
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:03:46
User entered 'No (N)'	System	30 Nov 2020 16:03:01

US3212394

Folder: SAE USA-US115-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:51:18

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 15:33:50
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:03:46
User entered 'No (N)'	System	30 Nov 2020 16:03:01

US3212394

Folder: SAE USA-US115-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:51:18

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 15:33:50
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:03:46
User entered 'Vicki'	System	30 Nov 2020 16:03:01

US3212394

Folder: SAE USA-US115-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:51:18

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 15:33:50
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:03:46
User entered 'Miller'	System	30 Nov 2020 16:03:01

US3212394

Folder: SAE USA-US115-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:51:18

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 15:33:50
User entered 'US'	System	30 Nov 2020 16:04:10

US3212394

Folder: SAE USA-US115-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:51:18

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	10 Dec 2020 16:13:05
User entered '1'	System	30 Nov 2020 16:04:10

US3212394

Folder: SAE USA-US115-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:51:18

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 15:33:50
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:03:46
User entered	System	30 Nov 2020 16:03:01
'USA-US115-2020-MRNA-1273-P301000014'		

US3212394

Folder: SAE USA-US115-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:51:18

Serious

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 15:33:50
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:03:46
User entered 'Yes (Y)'	System	30 Nov 2020 16:03:01

US3212394

Folder: SAE USA-US115-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:51:18

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 15:33:50
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:03:46
User entered 'No (N)'	System	30 Nov 2020 16:03:01

US3212394

Folder: SAE USA-US115-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:51:18

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 15:33:50
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:03:46
User entered 'No (N)'	System	30 Nov 2020 16:03:01

US3212394

Folder: SAE USA-US115-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:51:18

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 15:33:50
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:03:46
User entered 'Yes (Y)'	System	30 Nov 2020 16:03:01

US3212394

Folder: SAE USA-US115-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:51:18

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 15:33:50
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:03:46
User entered 'No (N)'	System	30 Nov 2020 16:03:01

US3212394

Folder: SAE USA-US115-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:51:18

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 15:33:50
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:03:46
User entered 'No (N)'	System	30 Nov 2020 16:03:01

US3212394

Folder: SAE USA-US115-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:51:18

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 15:33:50
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:03:46
User entered 'No (N)'	System	30 Nov 2020 16:03:01

US3212394

Folder: SAE USA-US115-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:51:18

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 15:33:50
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:03:46
User entered 'Vicki'	System	30 Nov 2020 16:03:01

US3212394

Folder: SAE USA-US115-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:51:18

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 15:33:50
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:03:46
User entered 'Miller'	System	30 Nov 2020 16:03:01

US3212394

Folder: SAE USA-US115-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:51:18

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 15:33:50
User entered 'US'	System	30 Nov 2020 16:04:10

US3212394

Folder: SAE USA-US115-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:51:18

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	10 Dec 2020 16:13:05
User entered '1'	System	30 Nov 2020 16:04:10

US3212394

Folder: SAE USA-US115-2020-MRNA-1273-P301000014

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:51:18

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 15:33:50
User entered '30/Nov/2020 16:04'	System	30 Nov 2020 16:04:10

US3212394

Folder: SAE USA-US115-2020-MRNA-1273-P301000014

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:51:18

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.	Vicki Miller (b) (4) [REDACTED]	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6) [REDACTED]	08 Dec 2020 15:33:50
User entered 'I'	(b) (4), (b) (6) [REDACTED]	30 Nov 2020 16:04:10

US3212394

Folder: SAE USA-US115-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:51:18

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 15:33:50
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:03:46
User entered	System	30 Nov 2020 16:03:01
'USA-US115-2020-MRNA-1273-P301000014'		

US3212394

Folder: SAE USA-US115-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:51:18

Serious

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 15:33:50
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:03:46
User entered 'Yes (Y)'	System	30 Nov 2020 16:03:01

US3212394

Folder: SAE USA-US115-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:51:18

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 15:33:50
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:03:46
User entered 'No (N)'	System	30 Nov 2020 16:03:01

US3212394

Folder: SAE USA-US115-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:51:18

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 15:33:50
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:03:46
User entered 'No (N)'	System	30 Nov 2020 16:03:01

US3212394

Folder: SAE USA-US115-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:51:18

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 15:33:50
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:03:46
User entered 'Yes (Y)'	System	30 Nov 2020 16:03:01

US3212394

Folder: SAE USA-US115-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:51:18

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 15:33:50
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:03:46
User entered 'No (N)'	System	30 Nov 2020 16:03:01

US3212394

Folder: SAE USA-US115-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:51:18

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 15:33:50
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:03:46
User entered 'No (N)'	System	30 Nov 2020 16:03:01

US3212394

Folder: SAE USA-US115-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:51:18

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 15:33:50
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:03:46
User entered 'No (N)'	System	30 Nov 2020 16:03:01

US3212394

Folder: SAE USA-US115-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:51:18

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 15:33:50
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:03:46
User entered 'Vicki'	System	30 Nov 2020 16:03:01

US3212394

Folder: SAE USA-US115-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:51:18

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 15:33:50
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:03:46
User entered 'Miller'	System	30 Nov 2020 16:03:01

US3212394

Folder: SAE USA-US115-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:51:18

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 15:33:50
User entered 'US'	System	30 Nov 2020 16:04:10

US3212394

Folder: SAE USA-US115-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:51:18

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	10 Dec 2020 16:13:05
User entered '1'	System	30 Nov 2020 16:04:10

US3212394

Folder: SAE USA-US115-2020-MRNA-1273-P301000014

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:51:18

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 05:45:18
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered '10/Dec/2020 10:13'	System	10 Dec 2020 16:13:05

US3212394

Folder: SAE USA-US115-2020-MRNA-1273-P301000014

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:51:18

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)	16 Apr 2021 05:45:18
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 15:32:39
User entered 'I'	(b) (4), (b) (6)	10 Dec 2020 16:13:05