

US3012329 (Prod: Benchmark Research-Austin)

Generated By: KC Joubran

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US3012329

Form: Participant Creation

Data signed: (b) (4) 26 Mar 2021 01:14:58

Generated On: 11 Aug 2021 21:53:26

[Participant ID](#)

US3012329

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

US3012329

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 21:11:09

Generated On: 11 Aug 2021 21:53:26

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	15 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 12 Feb 2021 21:11:08

Generated On: 11 Aug 2021 21:53:26

Date of Birth (MMM yyyy)	(b) (6) 1971
Age	49
Age Units	YEARS
Age (Derived)	49
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 12 Feb 2021 21:11:08

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Date of Informed Consent (<i>dd MMM yyyy</i>)	15 SEP 2020
Month and Year of Informed Consent (derived)	SEP 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/> Amendment 2 <input type="radio"/> Amendment 3 <input checked="" type="radio"/> Amendment 4 <input type="radio"/> Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/> Inclusion/Exclusion <input type="radio"/> Cohort Full <input type="radio"/> Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 12 Feb 2021 21:11:08

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 12 Feb 2021 21:11:09

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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) 12 Feb 2021 21:11:08

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Condition	UTERINE FIBROIDS
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 (2)

Data signed: (b) (4) 12 Feb 2021 21:11:08

Generated On: 11 Aug 2021 21:53:26

Condition	HYSTERECTOMY
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 (3)

Data signed: (b) (4) 12 Feb 2021 21:11:08

Generated On: 11 Aug 2021 21:53:26

Condition	POSTMENOPAUSAL
Start date (dd MMM yyyy)	UN UNK 1999
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 1999
Start Year (derived)	1999
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 12 Feb 2021 21:11:09

Generated On: 11 Aug 2021 21:53:26

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	15 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	15:54 (24 HR)
Vital Signs Date and Time (derived)	15 SEP 2020 15:54
Height (<i>xxx.x</i>)	63.0 in
Weight (<i>xxx.x</i>)	155.8 lb
BMI (<i>xxx.x</i>)	27.65644 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) 12 Feb 2021 21:11:09

Generated On: 11 Aug 2021 21:53:26

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

15 SEP 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 12 Feb 2021 21:11:08

Generated On: 11 Aug 2021 21:53:26

Date of assessment (*dd MMM yyyy*) 15 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*) UN UNK 1998

Date of surgery unknown False

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

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 12 Feb 2021 21:11:09

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Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 12 Feb 2021 21:11:09

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 21:11:09

Generated On: 11 Aug 2021 21:53:26

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	15 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 12 Feb 2021 21:11:09

Generated On: 11 Aug 2021 21:53:26

What was the date of randomization? (dd MMM yyyy) 15 SEP 2020

What was the participant's randomization number? 114216

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 12 Feb 2021 21:11:09

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Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Feb 2021 21:11:09

Generated On: 11 Aug 2021 21:53:26

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)	15 SEP 2020
Time of assessment (00:00-23:59)	15:54 (24 HR)
Vital Signs Date and Time (derived)	15 SEP 2020 15:54
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)	78 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 21:11:09

Generated On: 11 Aug 2021 21:53:26

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)	15 SEP 2020
Time of assessment (00:00-23:59)	18:12 (24 HR)
Vital Signs Date and Time (derived)	15 SEP 2020 18:12
Temperature (xxx.x)	98.6 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	121 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 21:11:09

Generated On: 11 Aug 2021 21:53:26

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 21:11:09

Generated On: 11 Aug 2021 21:53:26

Was study treatment given? Yes ☒ No ☐

If No, reason not given Participant declined due to Adverse Event ☐
Physician withheld dose due to Adverse Event ☐
Death ☐
Lost To Follow-Up ☐
Physician Decision ☐
Pregnancy ☐
Protocol Deviation ☐
Study Terminated by Sponsor ☐
Withdrawal of Consent by Participant ☐
Confirmed COVID-19 ☐
Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 15 SEP 2020

What was the treatment time? (00:00-23:59) 17:19 (24 HR)

Treatment Date and Time (derived) 15 SEP 2020 17:19

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 21:11:09

Generated On: 11 Aug 2021 21:53:26

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	15 SEP 2020
Collection time (00:00-23:59)	16:55 (24 HR)
Collection date and time (derived)	15 SEP 2020 16:55

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Feb 2021 21:11:09

Generated On: 11 Aug 2021 21:53:26

Collection date (dd MMM yyyy)			15 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	16:23	15 SEP 2020 16:23
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:11:09

Generated On: 11 Aug 2021 21:53:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 21:53:26

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

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 SEP 2020 18:04

PC Open Date & Time

15 SEP 2020 17:39

PC Close Date & Time

15 SEP 2020 20:09

US3012329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.6 °F

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

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

PC Time Stamp	15 SEP 2020 21:38
PC Open Date & Time	15 SEP 2020 21:04
PC Close Date & Time	16 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 21:53:26

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

98.6 °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 12:49

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3012329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 SEP 2020 12:01

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3012329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 21:53:26

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

18 SEP 2020 14:38

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3012329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °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

19 SEP 2020 13:11

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3012329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 21:53:26

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

20 SEP 2020 12:00

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3012329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 21:53:26

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

21 SEP 2020 12:01

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3012329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 21:53:26

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

15 SEP 2020 18:05

PC Open Date & Time

15 SEP 2020 17:39

PC Close Date & Time

15 SEP 2020 20:09

US3012329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

15 SEP 2020 21:39

PC Open Date & Time

15 SEP 2020 21:04

PC Close Date & Time

16 SEP 2020 11:59

US3012329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

16 SEP 2020 12:50

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3012329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

17 SEP 2020 12:01

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3012329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

18 SEP 2020 14:39

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3012329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

19 SEP 2020 13:11

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3012329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

20 SEP 2020 12:01

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3012329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

21 SEP 2020 12:01

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3012329

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:53:26

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 ☐

US3012329

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:53:26

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

No ☒

Yes ☐

PC Time stamp	15 SEP 2020 18:06
PC Open Date & Time	15 SEP 2020 17:39
PC Close Date & Time	15 SEP 2020 20:09

US3012329

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:53:26

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 ☐

US3012329

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:53:26

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

No ☒

Yes ☐

PC Time stamp	15 SEP 2020 21:40
PC Open Date & Time	15 SEP 2020 21:04
PC Close Date & Time	16 SEP 2020 11:59

US3012329

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:53:26

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)

US3012329

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:53:26

Yes <input type="checkbox"/>	
PC Time stamp	16 SEP 2020 12:51
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

US3012329

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:53:26

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 ☒

US3012329

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:53:26

Yes <input type="checkbox"/>	
PC Time stamp	17 SEP 2020 12:02
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

US3012329

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:53:26

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 ☒

US3012329

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:53:26

		Yes <input type="checkbox"/>
PC Time stamp	18 SEP 2020 14:39	
PC Open Date & Time	18 SEP 2020 12:00	
PC Close Date & Time	19 SEP 2020 11:59	

US3012329

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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51 of 2702

EAB) (1725)

US3012329

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:53:26

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

US3012329

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:53:26

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 ☒

US3012329

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:53:26

Yes <input type="checkbox"/>	
PC Time stamp	20 SEP 2020 12:01
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

US3012329

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:53:26

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 ☒

US3012329

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:53:26

Yes <input type="checkbox"/>	
PC Time stamp	21 SEP 2020 12:01
PC Open Date & Time	21 SEP 2020 12:00
PC Close Date & Time	22 SEP 2020 11:59

US3012329

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 21:11:08

Generated On: 11 Aug 2021 21:53:26

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3012329

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:11:08

Generated On: 11 Aug 2021 21:53:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3012329

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 21:11:08

Generated On: 11 Aug 2021 21:53:26

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3012329

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:11:08

Generated On: 11 Aug 2021 21:53:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3012329

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 21:11:08

Generated On: 11 Aug 2021 21:53:26

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

6 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3012329

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:11:08

Generated On: 11 Aug 2021 21:53:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3012329

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 21:11:09

Generated On: 11 Aug 2021 21:53:26

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	13 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3012329

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Feb 2021 21:11:09

Generated On: 11 Aug 2021 21:53:26

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	13 OCT 2020
Time of assessment (00:00-23:59)	16:14 (24 HR)
Vital Signs Date and Time (derived)	13 OCT 2020 16:14
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	79 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	125 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	79 mmHg
Diastolic Blood Pressure units	MMHG

US3012329

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 21:11:09

Generated On: 11 Aug 2021 21:53:26

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)	13 OCT 2020
Time of assessment (00:00-23:59)	18:07 (24 HR)
Vital Signs Date and Time (derived)	13 OCT 2020 18:07
Temperature (xxx.x)	98.4 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

US3012329

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 21:11:09

Generated On: 11 Aug 2021 21:53:26

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

13 OCT 2020

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

US3012329

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 21:11:09

Generated On: 11 Aug 2021 21:53:26

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 13 OCT 2020

What was the treatment time? (00:00-23:59) 17:29 (24 HR)

Treatment Date and Time (derived) 13 OCT 2020 17:29

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

US3012329

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 21:11:09

Generated On: 11 Aug 2021 21:53:26

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	13 OCT 2020
Collection time (00:00-23:59)	16:53 (24 HR)
Collection date and time (derived)	13 OCT 2020 16:53

US3012329

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Feb 2021 21:11:09

Generated On: 11 Aug 2021 21:53:26

Collection date (dd MMM yyyy)			13 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	16:45	13 OCT 2020 16:45
Nasopharyngeal Swab 2	No		

US3012329

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:11:09

Generated On: 11 Aug 2021 21:53:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3012329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 OCT 2020 18:03

PC Open Date & Time

13 OCT 2020 17:49

PC Close Date & Time

13 OCT 2020 20:19

US3012329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.6 °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	13 OCT 2020 23:34
PC Open Date & Time	13 OCT 2020 21:14
PC Close Date & Time	14 OCT 2020 11:59

US3012329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °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

14 OCT 2020 14:29

PC Open Date & Time

14 OCT 2020 12:00

PC Close Date & Time

15 OCT 2020 11:59

US3012329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 21:53:26

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

97.5 °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

15 OCT 2020 12:16

PC Open Date & Time

15 OCT 2020 12:00

PC Close Date & Time

16 OCT 2020 11:59

US3012329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 OCT 2020 14:10

PC Open Date & Time

16 OCT 2020 12:00

PC Close Date & Time

17 OCT 2020 11:59

US3012329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °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

17 OCT 2020 19:52

PC Open Date & Time

17 OCT 2020 12:00

PC Close Date & Time

18 OCT 2020 11:59

US3012329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °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

18 OCT 2020 20:28

PC Open Date & Time

18 OCT 2020 12:00

PC Close Date & Time

19 OCT 2020 11:59

US3012329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °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

19 OCT 2020 12:01

PC Open Date & Time

19 OCT 2020 12:00

PC Close Date & Time

20 OCT 2020 11:59

US3012329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

13 OCT 2020 18:03

PC Open Date & Time

13 OCT 2020 17:49

PC Close Date & Time

13 OCT 2020 20:19

US3012329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

13 OCT 2020 23:34

PC Open Date & Time

13 OCT 2020 21:14

PC Close Date & Time

14 OCT 2020 11:59

US3012329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

14 OCT 2020 14:29

PC Open Date & Time

14 OCT 2020 12:00

PC Close Date & Time

15 OCT 2020 11:59

US3012329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

15 OCT 2020 12:16

PC Open Date & Time

15 OCT 2020 12:00

PC Close Date & Time

16 OCT 2020 11:59

US3012329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

16 OCT 2020 14:10

PC Open Date & Time

16 OCT 2020 12:00

PC Close Date & Time

17 OCT 2020 11:59

US3012329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

17 OCT 2020 19:53

PC Open Date & Time

17 OCT 2020 12:00

PC Close Date & Time

18 OCT 2020 11:59

US3012329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

18 OCT 2020 20:28

PC Open Date & Time

18 OCT 2020 12:00

PC Close Date & Time

19 OCT 2020 11:59

US3012329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

19 OCT 2020 12:02

PC Open Date & Time

19 OCT 2020 12:00

PC Close Date & Time

20 OCT 2020 11:59

US3012329

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:53:26

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 ☐

US3012329

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:53:26

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

No ☒

Yes ☐

PC Time stamp	13 OCT 2020 18:04
PC Open Date & Time	13 OCT 2020 17:49
PC Close Date & Time	13 OCT 2020 20:19

US3012329

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:53:26

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 ☐

US3012329

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:53:26

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

No ☒

Yes ☐

PC Time stamp	13 OCT 2020 23:34
PC Open Date & Time	13 OCT 2020 21:14
PC Close Date & Time	14 OCT 2020 11:59

US3012329

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:53:26

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 ☒

US3012329

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:53:26

Yes <input type="checkbox"/>	
PC Time stamp	14 OCT 2020 14:30
PC Open Date & Time	14 OCT 2020 12:00
PC Close Date & Time	15 OCT 2020 11:59

US3012329

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3012329

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:53:26

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

US3012329

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:53:26

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)

US3012329

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:53:26

Yes <input type="checkbox"/>	
PC Time stamp	16 OCT 2020 14:11
PC Open Date & Time	16 OCT 2020 12:00
PC Close Date & Time	17 OCT 2020 11:59

US3012329

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:53:26

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 ☒

US3012329

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:53:26

Yes <input type="checkbox"/>	
PC Time stamp	17 OCT 2020 19:53
PC Open Date & Time	17 OCT 2020 12:00
PC Close Date & Time	18 OCT 2020 11:59

US3012329

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:53:26

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 ☒

US3012329

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:53:26

Yes <input type="checkbox"/>	
PC Time stamp	18 OCT 2020 20:28
PC Open Date & Time	18 OCT 2020 12:00
PC Close Date & Time	19 OCT 2020 11:59

US3012329

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3012329

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:53:26

Yes <input type="checkbox"/>	
PC Time stamp	19 OCT 2020 12:02
PC Open Date & Time	19 OCT 2020 12:00
PC Close Date & Time	20 OCT 2020 11:59

US3012329

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 21:11:08

Generated On: 11 Aug 2021 21:53:26

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3012329

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:11:08

Generated On: 11 Aug 2021 21:53:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3012329

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 21:11:08

Generated On: 11 Aug 2021 21:53:26

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

27 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3012329

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:11:08

Generated On: 11 Aug 2021 21:53:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3012329

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 21:11:08

Generated On: 11 Aug 2021 21:53:26

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

3 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3012329

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:11:08

Generated On: 11 Aug 2021 21:53:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3012329

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 21:11:09

Generated On: 11 Aug 2021 21:53:26

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	12 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

US3012329

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Feb 2021 21:11:09

Generated On: 11 Aug 2021 21:53:26

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	12 NOV 2020
Time of assessment (<i>00:00-23:59</i>)	15:32 (24 HR)
Vital Signs Date and Time (derived)	12 NOV 2020 15:32
Temperature (<i>xxx.x</i>)	98.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	81 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	131 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	82 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3012329

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 21:11:09

Generated On: 11 Aug 2021 21:53:26

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.

US3012329

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 21:11:09

Generated On: 11 Aug 2021 21:53:26

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	12 NOV 2020
Collection time (00:00-23:59)	15:38 (24 HR)
Collection date and time (derived)	12 NOV 2020 15:38

US3012329

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:11:09

Generated On: 11 Aug 2021 21:53:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3012329

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	17 NOV 2020 12:01:34
Patient Cloud Open Date & Time	15 NOV 2020 00:01
Patient Cloud Close Date & Time	19 NOV 2020 23:59

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

DAY 68

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 NOV 2020 00:02:07

Patient Cloud Open Date & Time

19 NOV 2020 00:01

Patient Cloud Close Date & Time

23 NOV 2020 23:59

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

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 checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	27 NOV 2020 17:56:37
Patient Cloud Open Date & Time	26 NOV 2020 00:01
Patient Cloud Close Date & Time	30 NOV 2020 23:59

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	03 DEC 2020 16:09:15
Patient Cloud Open Date & Time	03 DEC 2020 00:01
Patient Cloud Close Date & Time	07 DEC 2020 23:59

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

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 ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-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 DEC 2020 12:18:30

Patient Cloud Open Date & Time

10 DEC 2020 00:01

Patient Cloud Close Date & Time

14 DEC 2020 23:59

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

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	17 DEC 2020 04:07:06
Patient Cloud Open Date & Time	17 DEC 2020 00:01
Patient Cloud Close Date & Time	21 DEC 2020 23:59

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 DEC 2020 06:43:59

Patient Cloud Open Date & Time

24 DEC 2020 00:01

Patient Cloud Close Date & Time

28 DEC 2020 23:59

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	31 DEC 2020 06:31:59
Patient Cloud Open Date & Time	31 DEC 2020 00:01
Patient Cloud Close Date & Time	04 JAN 2021 23:59

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	11 JAN 2021 09:05:49
Patient Cloud Open Date & Time	07 JAN 2021 00:01
Patient Cloud Close Date & Time	11 JAN 2021 23:59

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	False
Chills	False
Cough	True
Shortness of breath	False
Difficulty breathing	False
Fatigue	False
Muscle aches	False
Body aches	False
Headache	True
New loss of taste	False
New loss of smell	False
Sore throat	True
Congestion	False
Runny nose	False
Nausea	False
Vomiting	False
Diarrhea	False
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	14 JAN 2021 11:48:24
Patient Cloud Open Date & Time	14 JAN 2021 00:01
Patient Cloud Close Date & Time	18 JAN 2021 23:59

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

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

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

Please contact your study clinic immediately. Click below to confirm that you have read this 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	24 JAN 2021 16:18:52
Patient Cloud Open Date & Time	21 JAN 2021 00:01
Patient Cloud Close Date & Time	25 JAN 2021 23:59

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

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

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

Please contact your study clinic immediately. Click below to confirm that you have read this 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	28 JAN 2021 10:59:43
Patient Cloud Open Date & Time	28 JAN 2021 00:01
Patient Cloud Close Date & Time	01 FEB 2021 23:59

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	04 FEB 2021 08:03:15
Patient Cloud Open Date & Time	04 FEB 2021 00:01
Patient Cloud Close Date & Time	08 FEB 2021 23:59

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

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

11 FEB 2021 17:12:06

Patient Cloud Open Date & Time

11 FEB 2021 00:01

Patient Cloud Close Date & Time

15 FEB 2021 23:59

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

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	18 FEB 2021 00:01:27
Patient Cloud Open Date & Time	18 FEB 2021 00:01
Patient Cloud Close Date & Time	22 FEB 2021 23:59

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

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

25 FEB 2021 20:37:31

Patient Cloud Open Date & Time

25 FEB 2021 00:01

Patient Cloud Close Date & Time

01 MAR 2021 23:59

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

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 <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 checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	04 MAR 2021 10:47:45
Patient Cloud Open Date & Time	04 MAR 2021 00:01
Patient Cloud Close Date & Time	08 MAR 2021 23:59

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	11 MAR 2021 04:11:26
Patient Cloud Open Date & Time	11 MAR 2021 00:01
Patient Cloud Close Date & Time	15 MAR 2021 23:59

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 MAR 2021 09:36:20

Patient Cloud Open Date & Time

18 MAR 2021 00:01

Patient Cloud Close Date & Time

22 MAR 2021 23:59

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

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 12:52:50
Patient Cloud Open Date & Time	25 MAR 2021 00:01
Patient Cloud Close Date & Time	29 MAR 2021 23:59

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

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	01 APR 2021 08:13:10
Patient Cloud Open Date & Time	01 APR 2021 00:01
Patient Cloud Close Date & Time	05 APR 2021 23:59

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 APR 2021 00:38:02

Patient Cloud Open Date & Time

08 APR 2021 00:01

Patient Cloud Close Date & Time

12 APR 2021 23:59

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

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 00:07:13

Patient Cloud Open Date & Time

15 APR 2021 00:01

Patient Cloud Close Date & Time

19 APR 2021 23:59

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 APR 2021 00:18:54

Patient Cloud Open Date & Time

22 APR 2021 00:01

Patient Cloud Close Date & Time

26 APR 2021 23:59

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

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

30 APR 2021 08:04:53

Patient Cloud Open Date & Time

29 APR 2021 00:01

Patient Cloud Close Date & Time

03 MAY 2021 23:59

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

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"/>

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

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

[Patient Cloud Close Date & Time](#)

10 MAY 2021 23:59

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

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 ☐

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

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

[Patient Cloud Open Date & Time](#)

13 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

17 MAY 2021 23:59

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

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

[Patient Cloud Open Date & Time](#)

20 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

24 MAY 2021 23:59

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

DAY 257

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

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

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

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

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

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

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

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

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

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

[Patient Cloud Open Date & Time](#)

27 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

31 MAY 2021 23:59

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

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"/>

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

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

03 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JUN 2021 23:59

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

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

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

14 JUN 2021 23:59

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

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 ☐

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

21 JUN 2021 23:59

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT	DAY 285
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUN 2021 23:59

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

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

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

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

[Patient Cloud Open Date & Time](#)

01 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

05 JUL 2021 23:59

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT	DAY 299
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

12 JUL 2021 23:59

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

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 ☐

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

19 JUL 2021 23:59

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT	DAY 313
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

26 JUL 2021 23:59

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

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"/>

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

02 AUG 2021 23:59

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

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 ☐

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

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

[Patient Cloud Open Date & Time](#)

05 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

09 AUG 2021 23:59

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

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

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

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

12 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

16 AUG 2021 23:59

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

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"/>

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

23 AUG 2021 23:59

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

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

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

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

26 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

30 AUG 2021 23:59

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

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 ☐

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

06 SEP 2021 23:59

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

DAY 362

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

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

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

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

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

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

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

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

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

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

[Patient Cloud Open Date & Time](#)

09 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

13 SEP 2021 23:59

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

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 ☐

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

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

[Patient Cloud Close Date & Time](#)

20 SEP 2021 23:59

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

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°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 ☐

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

27 SEP 2021 23:59

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

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 ☐

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

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

[Patient Cloud Close Date & Time](#)

04 OCT 2021 23:59

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT	DAY 390
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

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

07 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

11 OCT 2021 23:59

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

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 ☐

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

18 OCT 2021 23:59

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

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°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

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

[Patient Cloud Close Date & Time](#)

25 OCT 2021 23:59

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

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"/>

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

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

[Patient Cloud Close Date & Time](#)

01 NOV 2021 23:59

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

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 ☐

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

08 NOV 2021 23:59

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

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 ☐

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

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

[Patient Cloud Close Date & Time](#)

15 NOV 2021 23:59

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

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 ☐

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

22 NOV 2021 23:59

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT	DAY 439
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

29 NOV 2021 23:59

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

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"/>

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

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

[Patient Cloud Close Date & Time](#)

06 DEC 2021 23:59

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

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 ☐

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

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

[Patient Cloud Close Date & Time](#)

13 DEC 2021 23:59

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

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

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

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

[Patient Cloud Close Date & Time](#)

20 DEC 2021 23:59

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

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

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

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

[Patient Cloud Close Date & Time](#)

27 DEC 2021 23:59

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

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 ☐

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

03 JAN 2022 23:59

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT	DAY 481
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

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

[Patient Cloud Close Date & Time](#)

10 JAN 2022 23:59

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

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

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

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

13 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

17 JAN 2022 23:59

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

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 ☐

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

24 JAN 2022 23:59

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

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 ☐

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

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

[Patient Cloud Close Date & Time](#)

31 JAN 2022 23:59

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

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°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 ☐

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

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

03 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

07 FEB 2022 23:59

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

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

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

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

[Patient Cloud Close Date & Time](#)

14 FEB 2022 23:59

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

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 ☐

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

21 FEB 2022 23:59

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

DAY 530

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

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

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

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

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

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

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

28 FEB 2022 23:59

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

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 ☐

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

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

[Patient Cloud Close Date & Time](#)

07 MAR 2022 23:59

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT	DAY 544
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

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

[Patient Cloud Close Date & Time](#)

14 MAR 2022 23:59

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

DAY 551

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

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

[Patient Cloud Close Date & Time](#)

21 MAR 2022 23:59

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

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 ☐

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

28 MAR 2022 23:59

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

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 ☐

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 APR 2022 23:59

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

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 ☐

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

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

07 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

11 APR 2022 23:59

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

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 ☐

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

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

[Patient Cloud Close Date & Time](#)

18 APR 2022 23:59

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

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°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 ☐

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

25 APR 2022 23:59

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

02 MAY 2022 23:59

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

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"/>

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

09 MAY 2022 23:59

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

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°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

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

[Patient Cloud Close Date & Time](#)

16 MAY 2022 23:59

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

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 ☐
Yes ☐

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

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAY 2022 23:59

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

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°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

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

[Patient Cloud Close Date & Time](#)

30 MAY 2022 23:59

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

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"/>

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JUN 2022 23:59

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

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°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 ☐

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JUN 2022 23:59

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

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 ☐

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

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

[Patient Cloud Close Date & Time](#)

20 JUN 2022 23:59

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

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 ☐

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JUN 2022 23:59

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

DAY 656

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

04 JUL 2022 23:59

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

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°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 ☐

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

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

07 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

11 JUL 2022 23:59

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT	DAY 670
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

18 JUL 2022 23:59

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

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 ☐

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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 JUL 2022 00:01
Patient Cloud Close Date & Time	25 JUL 2022 23:59

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

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

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

01 AUG 2022 23:59

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

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"/>

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

08 AUG 2022 23:59

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT	DAY 698
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

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

[Patient Cloud Close Date & Time](#)

15 AUG 2022 23:59

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

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°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 ☐

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

22 AUG 2022 23:59

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

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

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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 AUG 2022 00:01
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Patient Cloud Close Date & Time	29 AUG 2022 23:59
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US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT	DAY 719
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

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

[Patient Cloud Close Date & Time](#)

05 SEP 2022 23:59

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

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 ☐
Yes ☐

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

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

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

[Patient Cloud Open Date & Time](#)

08 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

12 SEP 2022 23:59

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

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

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

19 SEP 2022 23:59

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

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 ☐
Yes ☐

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

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

26 SEP 2022 23:59

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

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="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"/>

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

03 OCT 2022 23:59

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

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 ☐

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

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

[Patient Cloud Close Date & Time](#)

10 OCT 2022 23:59

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

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

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

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

[Patient Cloud Close Date & Time](#)

17 OCT 2022 23:59

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

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

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

24 OCT 2022 23:59

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

DAY 775

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

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

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

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

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

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

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

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

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

31 OCT 2022 23:59

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

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 ☐

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

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

03 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

07 NOV 2022 23:59

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

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 ☐

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

14 NOV 2022 23:59

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

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"/>

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

21 NOV 2022 23:59

US3012329

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 11 Aug 2021 21:53:26

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 01:20:52

US3012329

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 19:36:43

Generated On: 11 Aug 2021 21:53:26

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

8 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3012329

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 19:36:43

Generated On: 11 Aug 2021 21:53:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3012329

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 26 Mar 2021 01:15:01

Generated On: 11 Aug 2021 21:53:26

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3012329

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 01:15:01

Generated On: 11 Aug 2021 21:53:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3012329

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 26 Mar 2021 01:15:08

Generated On: 11 Aug 2021 21:53:26

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 12 FEB 2021

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

Comments

If Contact Not Made, please provide Comments

US3012329

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 01:15:01

Generated On: 11 Aug 2021 21:53:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3012329

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 26 Mar 2021 01:15:08

Generated On: 11 Aug 2021 21:53:26

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3012329

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 01:15:08

Generated On: 11 Aug 2021 21:53:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3012329

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:53:26

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 _____

US3012329

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:53:26

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

US3012329

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:53:26

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.

US3012329

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:53:26

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

Collection date (<i>dd MMM yyyy</i>)	_____
Collection time (<i>00:00-23:59</i>)	_____
Collection date and time (derived)	_____

US3012329

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:53:26

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: COVID-19 Contact

Data signed: (b) (4) 26 Mar 2021 01:14:58

Generated On: 11 Aug 2021 21:53:26

Date of Contact	12 JAN 2021
Time of Contact	11:33
Date and Time of Contact (derived)	12 JAN 2021 11:33
Type of Contact	<div>Clinic Visit - Scheduled<input type="checkbox"/></div> <div>Clinical Visit - Unscheduled<input type="checkbox"/></div> <div>Safety Call<input checked="" type="checkbox"/></div> <div>Convalescent Tele-visit<input type="checkbox"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes<input checked="" type="checkbox"/></div> <div>No<input type="checkbox"/></div>

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (1)

Data signed: (b) (4) 26 Mar 2021 01:14:59

Generated On: 11 Aug 2021 21:53:26

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"/>

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (1)

Data signed: (b) (4) 26 Mar 2021 01:14:59

Generated On: 11 Aug 2021 21:53:26

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

Date	11 JAN 2021
------	-------------

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

O2 Saturation	ND - Not Done
---------------	---------------

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

Temperature	ND - Not Done
-------------	---------------

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

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

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

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

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EAB) (1725)

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Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (1)

Data signed: (b) (4) 26 Mar 2021 01:14:59

Generated On: 11 Aug 2021 21:53:26

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

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (1)

Data signed: (b) (4) 26 Mar 2021 01:14:59

Generated On: 11 Aug 2021 21:53:26

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"/>

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (2)

Data signed: (b) (4) 26 Mar 2021 01:14:59

Generated On: 11 Aug 2021 21:53:26

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"/>

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Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (2)

Data signed: (b) (4) 26 Mar 2021 01:14:59

Generated On: 11 Aug 2021 21:53:26

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	12 JAN 2021	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (2)

Data signed: (b) (4) 26 Mar 2021 01:14:59

Generated On: 11 Aug 2021 21:53:26

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

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (2)

Data signed: (b) (4) 26 Mar 2021 01:14:59

Generated On: 11 Aug 2021 21:53:26

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (3)

Data signed: (b) (4) 26 Mar 2021 01:14:59

Generated On: 11 Aug 2021 21:53:26

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"/>

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (3)

Data signed: (b) (4) 26 Mar 2021 01:14:59

Generated On: 11 Aug 2021 21:53:26

	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 JAN 2021	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (3)

Data signed: (b) (4) 26 Mar 2021 01:14:59

Generated On: 11 Aug 2021 21:53:26

	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"/>

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (3)

Data signed: (b) (4) 26 Mar 2021 01:14:59

Generated On: 11 Aug 2021 21:53:26

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 12 Jan 2021

Form: Symptom Log (4)

Data signed: (b) (4) 26 Mar 2021 01:14:59

Generated On: 11 Aug 2021 21:53:26

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 12 Jan 2021

Form: Symptom Log (4)

Data signed: (b) (4) 26 Mar 2021 01:14:59

Generated On: 11 Aug 2021 21:53:26

	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 JAN 2021
------	-------------

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

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

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

Temperature	98.6 F
-------------	--------

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

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

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

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

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Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (4)

Data signed: (b) (4) 26 Mar 2021 01:14:59

Generated On: 11 Aug 2021 21:53:26

	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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (4)

Data signed: (b) (4) 26 Mar 2021 01:14:59

Generated On: 11 Aug 2021 21:53:26

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

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Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (5)

Data signed: (b) (4) 26 Mar 2021 01:14:59

Generated On: 11 Aug 2021 21:53:26

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 12 Jan 2021

Form: Symptom Log (5)

Data signed: (b) (4) 26 Mar 2021 01:14:59

Generated On: 11 Aug 2021 21:53:26

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

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

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

O2 Saturation	99 %
---------------	------

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

Temperature	101.2 F
-------------	---------

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

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

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

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

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EAB) (1725)

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Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (5)

Data signed: (b) (4) 26 Mar 2021 01:14:59

Generated On: 11 Aug 2021 21:53:26

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

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Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (5)

Data signed: (b) (4) 26 Mar 2021 01:14:59

Generated On: 11 Aug 2021 21:53:26

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

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Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (6)

Data signed: (b) (4) 26 Mar 2021 01:14:59

Generated On: 11 Aug 2021 21:53:26

Symptom Day

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

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Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (6)

Data signed: (b) (4) 26 Mar 2021 01:14:59

Generated On: 11 Aug 2021 21:53:26

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	16 JAN 2021	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	101 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (6)

Data signed: (b) (4) 26 Mar 2021 01:14:59

Generated On: 11 Aug 2021 21:53:26

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

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Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (6)

Data signed: (b) (4) 26 Mar 2021 01:14:59

Generated On: 11 Aug 2021 21:53:26

Nasal Congestion	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" 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 12 Jan 2021

Form: Symptom Log (7)

Data signed: (b) (4) 26 Mar 2021 01:14:59

Generated On: 11 Aug 2021 21:53:26

Symptom Day

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

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Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (7)

Data signed: (b) (4) 26 Mar 2021 01:14:59

Generated On: 11 Aug 2021 21:53:26

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	17 JAN 2021	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	100 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (7)

Data signed: (b) (4) 26 Mar 2021 01:14:59

Generated On: 11 Aug 2021 21:53:26

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

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Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (7)

Data signed: (b) (4) 26 Mar 2021 01:14:59

Generated On: 11 Aug 2021 21:53:26

Nasal Congestion	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" 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 12 Jan 2021

Form: Symptom Log (8)

Data signed: (b) (4) 26 Mar 2021 01:14:59

Generated On: 11 Aug 2021 21:53:26

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 12 Jan 2021

Form: Symptom Log (8)

Data signed: (b) (4) 26 Mar 2021 01:14:59

Generated On: 11 Aug 2021 21:53:26

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

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

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

O2 Saturation	99 %
---------------	------

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

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

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

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Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (8)

Data signed: (b) (4) 26 Mar 2021 01:14:59

Generated On: 11 Aug 2021 21:53:26

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

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Form: Symptom Log (8)

Data signed: (b) (4) 26 Mar 2021 01:14:59

Generated On: 11 Aug 2021 21:53:26

Nasal Congestion	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input type="radio"/>
	Mild	<input checked="" 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 type="radio"/>
	Mild	<input checked="" 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 (9)

Data signed: (b) (4) 26 Mar 2021 01:14:59

Generated On: 11 Aug 2021 21:53:26

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 12 Jan 2021

Form: Symptom Log (9)

Data signed: (b) (4) 26 Mar 2021 01:14:59

Generated On: 11 Aug 2021 21:53:26

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

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

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

O2 Saturation	87 %
---------------	------

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

Temperature	ND - Not Done
-------------	---------------

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

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

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

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

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Form: Symptom Log (9)

Data signed: (b) (4) 26 Mar 2021 01:14:59

Generated On: 11 Aug 2021 21:53:26

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

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Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (9)

Data signed: (b) (4) 26 Mar 2021 01:14:59

Generated On: 11 Aug 2021 21:53:26

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

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Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (10)

Data signed: (b) (4) 26 Mar 2021 01:14:59

Generated On: 11 Aug 2021 21:53:26

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 12 Jan 2021

Form: Symptom Log (10)

Data signed: (b) (4) 26 Mar 2021 01:14:59

Generated On: 11 Aug 2021 21:53:26

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	20 JAN 2021	
Assessment Not Done	False	
O2 Saturation	94 %	
O2 Saturation Units	%	
Temperature	97.0 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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (10)

Data signed: (b) (4) 26 Mar 2021 01:14:59

Generated On: 11 Aug 2021 21:53:26

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

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Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (10)

Data signed: (b) (4) 26 Mar 2021 01:14:59

Generated On: 11 Aug 2021 21:53:26

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

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Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (11)

Data signed: (b) (4) 26 Mar 2021 01:14:59

Generated On: 11 Aug 2021 21:53:26

Symptom Day

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

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Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (11)

Data signed: (b) (4) 26 Mar 2021 01:14:59

Generated On: 11 Aug 2021 21:53:26

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

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

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

O2 Saturation	95 %
---------------	------

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

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

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

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Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (11)

Data signed: (b) (4) 26 Mar 2021 01:14:59

Generated On: 11 Aug 2021 21:53:26

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

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Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (11)

Data signed: (b) (4) 26 Mar 2021 01:14:59

Generated On: 11 Aug 2021 21:53:26

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

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Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (12)

Data signed: (b) (4) 26 Mar 2021 01:14:59

Generated On: 11 Aug 2021 21:53:26

Symptom Day

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

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Form: Symptom Log (12)

Data signed: (b) (4) 26 Mar 2021 01:14:59

Generated On: 11 Aug 2021 21:53:26

	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 JAN 2021	
Assessment Not Done	False	
O2 Saturation	93 %	
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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (12)

Data signed: (b) (4) 26 Mar 2021 01:14:59

Generated On: 11 Aug 2021 21:53:26

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

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Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (12)

Data signed: (b) (4) 26 Mar 2021 01:14:59

Generated On: 11 Aug 2021 21:53:26

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

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Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (13)

Data signed: (b) (4) 26 Mar 2021 01:14:59

Generated On: 11 Aug 2021 21:53:26

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 12 Jan 2021

Form: Symptom Log (13)

Data signed: (b) (4) 26 Mar 2021 01:14:59

Generated On: 11 Aug 2021 21:53:26

	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 JAN 2021	
Assessment Not Done	True	
O2 Saturation	<input type="text"/>	
O2 Saturation Units	<input type="text"/>	
Temperature	<input type="text"/>	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (13)

Data signed: (b) (4) 26 Mar 2021 01:14:59

Generated On: 11 Aug 2021 21:53:26

	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 12 Jan 2021

Form: Symptom Log (13)

Data signed: (b) (4) 26 Mar 2021 01:14:59

Generated On: 11 Aug 2021 21:53:26

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 12 Jan 2021

Form: Symptom Log (14)

Data signed: (b) (4) 26 Mar 2021 01:14:59

Generated On: 11 Aug 2021 21:53:26

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 12 Jan 2021

Form: Symptom Log (14)

Data signed: (b) (4) 26 Mar 2021 01:14:59

Generated On: 11 Aug 2021 21:53:26

	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 JAN 2021
------	-------------

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

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

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

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

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

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

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

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

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EAB) (1725)

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Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (14)

Data signed: (b) (4) 26 Mar 2021 01:14:59

Generated On: 11 Aug 2021 21:53:26

	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 12 Jan 2021

Form: Symptom Log (14)

Data signed: (b) (4) 26 Mar 2021 01:14:59

Generated On: 11 Aug 2021 21:53:26

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 12 Jan 2021

Form: Symptom Log (15)

Data signed: (b) (4) 26 Mar 2021 01:14:59

Generated On: 11 Aug 2021 21:53:26

Symptom Day

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

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Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (15)

Data signed: (b) (4) 26 Mar 2021 01:14:59

Generated On: 11 Aug 2021 21:53:26

	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 JAN 2021
------	-------------

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

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

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

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

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

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

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

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

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EAB) (1725)

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Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (15)

Data signed: (b) (4) 26 Mar 2021 01:14:59

Generated On: 11 Aug 2021 21:53:26

	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 12 Jan 2021

Form: Symptom Log (15)

Data signed: (b) (4) 26 Mar 2021 01:14:59

Generated On: 11 Aug 2021 21:53:26

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 12 Jan 2021

Form: Symptom Log (16)

Data signed: (b) (4) 26 Mar 2021 01:14:59

Generated On: 11 Aug 2021 21:53:26

Symptom Day

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

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Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (16)

Data signed: (b) (4) 26 Mar 2021 01:14:59

Generated On: 11 Aug 2021 21:53:26

	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 JAN 2021
------	-------------

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 12 Jan 2021

Form: Symptom Log (16)

Data signed: (b) (4) 26 Mar 2021 01:14:59

Generated On: 11 Aug 2021 21:53:26

	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 12 Jan 2021

Form: Symptom Log (16)

Data signed: (b) (4) 26 Mar 2021 01:14:59

Generated On: 11 Aug 2021 21:53:26

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 12 Jan 2021

Form: COVID Diagnostic Test

Data signed: (b) (4) 26 Mar 2021 01:14:58

Generated On: 11 Aug 2021 21:53:26

Date of Visit	13 JAN 2021
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of Test	13 JAN 2021
Type of Test Performed	Nasopharyngeal Swab <input checked="" type="radio"/> Nasal Swab <input type="radio"/> Saliva Test <input type="radio"/> Other <input type="radio"/>
Other, specify	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If yes, provide lab information below	
Lab/ Institution Test Performed	
CLIA Certified?	Yes <input type="radio"/> No <input type="radio"/>
COVID-19 Positive (CSA Programming Field Only)	1

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Folder: Covid-19 Assessment 12 Jan 2021

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 22 Apr 2021 23:56:31

Generated On: 11 Aug 2021 21:53:26

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

If Yes, provide:

Start Date _____

End Date _____

Respiratory Rate _____

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

If Yes, provide:

Start Date _____

End Date _____

Heart Rate _____

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

If Yes, provide:

Start Date 19 JAN 2021

End Date 22 JAN 2021

Oxygen Saturation 87 %

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

If Yes, provide:

Start Date _____

End Date _____

PaO₂ _____

Did the subject have Respiratory failure? Yes ☐ No ☒

Start Date _____

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

Start Date _____

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Folder: Covid-19 Assessment 12 Jan 2021

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 22 Apr 2021 23:56:31

Generated On: 11 Aug 2021 21:53:26

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

Ventilator Support:

High-Flow Oxygen? Yes ☐
No ☐

Start Date

End Date

Non-Invasive Ventilation? Yes ☐
No ☐

Start Date

End Date

Mechanical Ventilation? Yes ☐
No ☐

Start Date

End Date

ECMO? Yes ☐
No ☐

Start Date

End Date

Evidence of Shock:

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg Yes ☐
No ☒

Start Date

End Date

Evidence of Shock Requires Vasopressors Yes ☐
No ☒

Start Date

End Date

Acute Renal Dysfunction? Yes ☐
No ☒

Start Date

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Folder: Covid-19 Assessment 12 Jan 2021

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 22 Apr 2021 23:56:31

Generated On: 11 Aug 2021 21:53:26

Hepatic Dysfunction? Yes ☐
No ☒

Start Date

Neurologic Dysfunction? Yes ☐
No ☒

Start Date

Evidence of Pneumonia:

Clinical Evidence Yes ☐
No ☒

Date of Assessment

Radiographical Evidence Yes ☐
No ☒

Date of Assessment

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

Start Date

End Date

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Folder: Covid-19 Assessment 12 Jan 2021

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 26 Mar 2021 01:14:59

Generated On: 11 Aug 2021 21:53:26

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

US3012329

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 08 Apr 2021 15:00:49

Generated On: 11 Aug 2021 21:53:26

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	15 JAN 2021
Day 5	Yes	17 JAN 2021
Day 7	Yes	19 JAN 2021
Day 9	Yes	21 JAN 2021
Day 14	Yes	26 JAN 2021
Day 21	Yes	02 FEB 2021
Day 28	Yes	22 FEB 2021

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Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 26 Mar 2021 01:15:00

Generated On: 11 Aug 2021 21:53:26

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	13 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	SICKD1

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Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 26 Mar 2021 01:15:00

Generated On: 11 Aug 2021 21:53:26

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	13 JAN 2021
Time of assessment (00:00-23:59)	11:20 (24 HR)
Vital Signs Date and Time (derived)	13 JAN 2021 11:20
Height (xxx.x)	66.0 in
Weight (xxx.x)	161.4 lb
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	133 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	90 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3012329

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Mar 2021 01:15:00

Generated On: 11 Aug 2021 21:53:26

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

13 JAN 2021

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

US3012329

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 26 Mar 2021 01:15:00

Generated On: 11 Aug 2021 21:53:26

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

13 JAN 2021

US3012329

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 26 Mar 2021 01:14:58

Generated On: 11 Aug 2021 21:53:26

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	22 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD28

US3012329

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 26 Mar 2021 01:14:58

Generated On: 11 Aug 2021 21:53:26

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	22 FEB 2021
Time of assessment (00:00-23:59)	16:54 (24 HR)
Vital Signs Date and Time (derived)	22 FEB 2021 16:54
Height (xxx.x)	66 in
Weight (xxx.x)	158.2 lb
Temperature (xxx.x)	98.9 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	97 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	91 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3012329

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Mar 2021 01:14:58

Generated On: 11 Aug 2021 21:53:26

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

22 FEB 2021

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

US3012329

Folder: Convalescence Visit Day 28 (1)

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

Data signed: (b) (4) 26 Mar 2021 01:14:58

Generated On: 11 Aug 2021 21:53:26

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

22 FEB 2021

US3012329

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

Form: Visit Date

Data signed: (b) (4) 26 Mar 2021 01:15:00

Generated On: 11 Aug 2021 21:53:26

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

Visit date (dd MMM yyyy)	03 MAR 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3012329

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

Form: Unblinding

Data signed: (b) (4) 09 Apr 2021 20:47:50

Generated On: 11 Aug 2021 21:53:26

Date of updated informed consent (<i>dd MMM yyyy</i>)	03 MAR 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding (<i>dd MMM yyyy</i>)	03 MAR 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3012329

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 26 Mar 2021 01:15:00

Generated On: 11 Aug 2021 21:53:26

Height	62.75 in
Weight	160.2 lb
BMI (xxx.x)	28.66454

US3012329

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 26 Mar 2021 01:15:00

Generated On: 11 Aug 2021 21:53:26

Height	62.75 in
Weight	160.2 lb
BMI (xxx.x)	28.66454
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)	03 MAR 2021
Time of assessment (00:00-23:59)	14:25 (24 HR)
Vital Signs Date and Time (derived)	03 MAR 2021 14:25
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	83 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	131 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	79 mmHg
Diastolic Blood Pressure units	MMHG

US3012329

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 26 Mar 2021 01:15:00

Generated On: 11 Aug 2021 21:53:26

Height	62.75 in
Weight	160.2 lb
BMI (xxx.x)	28.66454
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)	03 MAR 2021
Time of assessment (00:00-23:59)	16:38 (24 HR)
Vital Signs Date and Time (derived)	03 MAR 2021 16:38
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

US3012329

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

Form: Physical Examination

Data signed: (b) (4) 26 Mar 2021 01:15:00

Generated On: 11 Aug 2021 21:53:26

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

03 MAR 2021

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

US3012329

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

Form: Exposure

Data signed: (b) (4) 26 Mar 2021 01:15:00

Generated On: 11 Aug 2021 21:53:26

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 03 MAR 2021

What was the treatment time? (00:00-23:59) 16:03 (24 HR)

Treatment Date and Time (derived) 03 MAR 2021 16:03

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

US3012329

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Mar 2021 01:15:00

Generated On: 11 Aug 2021 21:53:26

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	03 MAR 2021
Collection time (00:00-23:59)	15:22 (24 HR)
Collection date and time (derived)	03 MAR 2021 15:22

US3012329

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 26 Mar 2021 01:15:00

Generated On: 11 Aug 2021 21:53:26

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	03 MAR 2021
Collection time (00:00 - 23:59)	14:30
Collection Date and Time (derived)	03 MAR 2021 14:30

US3012329

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

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 01:15:00

Generated On: 11 Aug 2021 21:53:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3012329

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 26 Mar 2021 01:15:08

Generated On: 11 Aug 2021 21:53:26

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3012329

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 01:15:08

Generated On: 11 Aug 2021 21:53:26

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

US3012329

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 08 Apr 2021 15:00:49

Generated On: 11 Aug 2021 21:53:26

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	29 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3012329

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 08 Apr 2021 15:00:49

Generated On: 11 Aug 2021 21:53:26

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)	29 MAR 2021
Time of assessment (00:00-23:59)	12:13 (24 HR)
Vital Signs Date and Time (derived)	29 MAR 2021 12:13
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)	77 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	83 mmHg
Diastolic Blood Pressure units	MMHG

US3012329

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 08 Apr 2021 15:00:49

Generated On: 11 Aug 2021 21:53:26

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)	29 MAR 2021
Time of assessment (00:00-23:59)	13:22 (24 HR)
Vital Signs Date and Time (derived)	29 MAR 2021 13:22
Temperature (xxx.x)	98.9 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	73 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	137 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

US3012329

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 08 Apr 2021 15:00:49

Generated On: 11 Aug 2021 21:53:26

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

29 MAR 2021

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

US3012329

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 08 Apr 2021 15:00:49

Generated On: 11 Aug 2021 21:53:26

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 29 MAR 2021

What was the treatment time? (00:00-23:59) 12:47 (24 HR)

Treatment Date and Time (derived) 29 MAR 2021 12:47

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

US3012329

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 08 Apr 2021 15:00:49

Generated On: 11 Aug 2021 21:53:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3012329

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 08 Apr 2021 15:00:49

Generated On: 11 Aug 2021 21:53:26

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

6 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3012329

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 08 Apr 2021 15:00:49

Generated On: 11 Aug 2021 21:53:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3012329

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 30 Apr 2021 15:32:10

Generated On: 11 Aug 2021 21:53:26

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	29 APR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57

US3012329

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 30 Apr 2021 15:32:10

Generated On: 11 Aug 2021 21:53:26

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	29 APR 2021
Time of assessment (<i>00:00-23:59</i>)	16:51 (24 HR)
Vital Signs Date and Time (derived)	29 APR 2021 16:51
Temperature (<i>xxx.x</i>)	98.5 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	89 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	139 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	84 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3012329

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 30 Apr 2021 15:32:10

Generated On: 11 Aug 2021 21:53:26

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.

US3012329

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 30 Apr 2021 15:32:10

Generated On: 11 Aug 2021 21:53:26

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	29 APR 2021
Collection time (00:00-23:59)	16:57 (24 HR)
Collection date and time (derived)	29 APR 2021 16:57

US3012329

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 12 Mar 2021 19:42:47

Generated On: 11 Aug 2021 21:53:26

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3012329

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 30 Apr 2021 15:32:10

Generated On: 11 Aug 2021 21:53:26

AEID	USA-US006-2021-MRNA-1273-P30 1000003
Adverse event	COVID-19
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Start date (dd MMM yyyy)	11 JAN 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	25 JAN 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 30 Apr 2021 15:32:10

Generated On: 11 Aug 2021 21:53:26

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

US3012329

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 30 Apr 2021 15:32:10

Generated On: 11 Aug 2021 21:53:26

SUBJECT REPORTED TO ER ON
25-JAN-2021 WITH SHORTNESS
OF BREATH AND CHEST PAIN,
WAS TREATED AND RELEASED
AFTER 4 HOURS. CON-MEDS
USED TO TREAT ENTERED.

RECORDS FROM HOSPITAL
RECEIVED AND SUBJECT WAS
NOT ADMITTED.

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)	0

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 30 Apr 2021 15:32:10

Generated On: 11 Aug 2021 21:53:26

AEID

Adverse event

URINARY TRACT INFECTION

Was this a medically-attended AE?

Yes ☐

No ☒

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

7 MAR 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

11 MAR 2021

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) 30 Apr 2021 15:32:10

Generated On: 11 Aug 2021 21:53:26

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	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	_____

US3012329

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 30 Apr 2021 15:32:10

Generated On: 11 Aug 2021 21:53:26

AEID	
Adverse event	HPV
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)	21 MAR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input 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 (4)

Data signed: (b) (4) 30 Apr 2021 15:32:10

Generated On: 11 Aug 2021 21:53:26

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 checked="" type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 26 Mar 2021 01:14:58

Generated On: 11 Aug 2021 21:53:26

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

Yes ☒

No ☐

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 16 Apr 2021 18:18:05

Generated On: 11 Aug 2021 21:53:26

Name of Medication ZITHROMAX

Prophylaxis Yes ☐
No ☒

Indication COVID-19 INFECTION (AE #1)

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 16 Apr 2021 18:18:05

Generated On: 11 Aug 2021 21:53:26

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	19 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	06 FEB 2021	
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"/>

US3012329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 16 Apr 2021 18:18:05

Generated On: 11 Aug 2021 21:53:26

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication COVID-19 INFECTION (AE #1)

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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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 16 Apr 2021 18:18:05

Generated On: 11 Aug 2021 21:53:26

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	19 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		06 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 16 Apr 2021 18:18:05

Generated On: 11 Aug 2021 21:53:26

Name of Medication PREDNISONE

Prophylaxis Yes ☐
No ☒

Indication COVID-19 INFECTION (AE #1)

Dose per administration 80

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) 16 Apr 2021 18:18:05

Generated On: 11 Aug 2021 21:53:26

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		19 JAN 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		24 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 16 Apr 2021 18:18:05

Generated On: 11 Aug 2021 21:53:26

Name of Medication IBUPROFEN

Prophylaxis Yes ☐
No ☒

Indication COVID-19 INFECTION (AE #2)

Dose per administration 400

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 16 Apr 2021 18:18:05

Generated On: 11 Aug 2021 21:53:26

	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 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		06 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 16 Apr 2021 18:18:05

Generated On: 11 Aug 2021 21:53:26

Name of Medication DEXAMETHASONE

Prophylaxis Yes ☐
No ☒

Indication COVID-19 INFECTION (AE #2)

Dose per administration 200

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) 16 Apr 2021 18:18:05

Generated On: 11 Aug 2021 21:53:26

	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 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		06 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 16 Apr 2021 18:18:05

Generated On: 11 Aug 2021 21:53:26

Name of Medication BENZENOTATE

Prophylaxis Yes ☐
No ☒

Indication COVID-19 INFECTION (AE #2)

Dose per administration 200

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 16 Apr 2021 18:18:05

Generated On: 11 Aug 2021 21:53:26

	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 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	06 FEB 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 16 Apr 2021 18:18:05

Generated On: 11 Aug 2021 21:53:26

Name of Medication BACTRIM DS

Prophylaxis Yes ☐
No ☒

Indication URINARY TRACT INFECTION

Dose per administration 160/800

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 (7)

Data signed: (b) (4) 16 Apr 2021 18:18:05

Generated On: 11 Aug 2021 21:53:26

	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)	8 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	11 MAR 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3012329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 16 Apr 2021 18:18:05

Generated On: 11 Aug 2021 21:53:26

Name of Medication ADVIL (IBUPROFEN)

Prophylaxis Yes ☐
No ☒

Indication HEADACHE, BODY ACHES (DUE TO COVID INFECTION (AE #1))

Dose per administration 400

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 16 Apr 2021 18:18:05

Generated On: 11 Aug 2021 21:53:26

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	11 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		12 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3012329

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 26 Mar 2021 01:14:58

Generated On: 11 Aug 2021 21:53:26

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 21:53:26

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

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

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 21:53:26

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 ☐

US3012329

Folder: SAE USA-US006-2021-MRNA-1273-P301000003

Form: Safety Report Form

Data signed: (b) (4) 26 Mar 2021 01:15:00

Generated On: 11 Aug 2021 21:53:26

SAEID	USA-US006-2021-MRNA-1273-P301000003
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	LAURENCE
Investigator's Last Name	CHU
Site Address: Street	3100 RED RIVER STREET
Site Address: City	AUSTIN
Site Address: State	TX
Site Address: Postal Code	78705
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5

US3012329

Folder: SAE USA-US006-2021-MRNA-1273-P301000003

Form: Safety Report Form (1)

Data signed: (b) (4) 26 Mar 2021 01:15:00

Generated On: 11 Aug 2021 21:53:26

SAEID	USA-US006-2021-MRNA-1273-P301000003
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	LAURENCE
Investigator's Last Name	CHU
Site Address: Street	3100 RED RIVER STREET
Site Address: City	AUSTIN
Site Address: State	TX
Site Address: Postal Code	78705
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	20/JAN/2021 08:27
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

US3012329

Folder: SAE USA-US006-2021-MRNA-1273-P301000003

Form: Safety Report Form (2)

Data signed: (b) (4) 26 Mar 2021 01:15:00

Generated On: 11 Aug 2021 21:53:26

SAEID	USA-US006-2021-MRNA-1273-P301000003
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	LAURENCE
Investigator's Last Name	CHU
Site Address: Street	3100 RED RIVER STREET
Site Address: City	AUSTIN
Site Address: State	TX
Site Address: Postal Code	78705
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	28/JAN/2021 16:35
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

US3012329

Folder: SAE USA-US006-2021-MRNA-1273-P301000003

Form: Safety Report Form (3)

Data signed: (b) (4) 26 Mar 2021 01:15:00

Generated On: 11 Aug 2021 21:53:26

SAEID	USA-US006-2021-MRNA-1273-P301000003
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	LAURENCE
Investigator's Last Name	CHU
Site Address: Street	3100 RED RIVER STREET
Site Address: City	AUSTIN
Site Address: State	TX
Site Address: Postal Code	78705
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	12/FEB/2021 12:29
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

US3012329

Folder: SAE USA-US006-2021-MRNA-1273-P301000003

Form: Safety Report Form (4)

Data signed: (b) (4) 26 Mar 2021 01:15:00

Generated On: 11 Aug 2021 21:53:26

SAEID	USA-US006-2021-MRNA-1273-P301000003
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	LAURENCE
Investigator's Last Name	CHU
Site Address: Street	3100 RED RIVER STREET
Site Address: City	AUSTIN
Site Address: State	TX
Site Address: Postal Code	78705
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	12/FEB/2021 13:08
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

US3012329

Folder: SAE USA-US006-2021-MRNA-1273-P301000003

Form: Safety Report Form (5)

Data signed: (b) (4) 26 Mar 2021 01:15:00

Generated On: 11 Aug 2021 21:53:26

SAEID	USA-US006-2021-MRNA-1273-P301000003
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	LAURENCE
Investigator's Last Name	CHU
Site Address: Street	3100 RED RIVER STREET
Site Address: City	AUSTIN
Site Address: State	TX
Site Address: Postal Code	78705
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	04/MAR/2021 08:59
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

US3012329 (Prod: Benchmark Research-Austin)

US3012329

Form: Participant Creation

Generated On: 11 Aug 2021 21:53:26

[Participant ID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 13:23:00
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered 'US3012329'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	15 Sep 2020 20:39:25

US3012329

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 21:53:26

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:04:08
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered 'Yes (Y)'	Jennifer Leyva (b) (4)	15 Sep 2020 22:58:44

US3012329

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 21:53:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:04:08
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered '15 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	15 Sep 2020 20:39:26

US3012329

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 21:53:26

[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 12:04:08
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered 'Clinic (Clinic)'	Jennifer Leyva (b) (4)	15 Sep 2020 22:58:44

US3012329

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 21:53:26

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:04:08
User entered 'SCRN'	System	15 Sep 2020 22:58:44

US3012329

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:53:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:04:08
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered (b) (6) 1971'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	15 Sep 2020 20:39:27

US3012329

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:53:26

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:04:08
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered '49'	Jennifer Leyva (b) (4)	15 Sep 2020 22:58:55

US3012329

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:53:26

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:04:08
User entered 'YEARS'	System	15 Sep 2020 22:58:55

US3012329

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:53:26

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:04:08
User entered '49'	System	15 Sep 2020 22:59:36

US3012329

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:53:26

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:04:08
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered 'Female (F)'	Jennifer Leyva (b) (4)	15 Sep 2020 22:58:55

US3012329

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:53:26

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:04:08
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Jennifer Leyva (b) (4)	15 Sep 2020 22:58:55

US3012329

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:53:26

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:04:08
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered 'I'	Jennifer Leyva (b) (4)	15 Sep 2020 22:58:55

US3012329

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:53:26

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:04:08
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered '0'	Jennifer Leyva (b) (4)	15 Sep 2020 22:58:55

US3012329

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:53:26

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:04:08
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered '0'	Jennifer Leyva (b) (4)	15 Sep 2020 22:58:55

US3012329

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:53:26

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:04:08
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered '0'	Jennifer Leyva (b) (4)	15 Sep 2020 22:58:55

US3012329

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:53:26

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:04:08
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered '0'	Jennifer Leyva (b) (4)	15 Sep 2020 22:58:55

US3012329

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:53:26

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:04:08
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered '0'	Jennifer Leyva (b) (4)	15 Sep 2020 22:58:55

US3012329

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:53:26

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:04:08
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered empty.	Jennifer Leyva (b) (4)	15 Sep 2020 22:58:55

US3012329

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:53:26

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:04:08
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered '0'	Jennifer Leyva (b) (4)	15 Sep 2020 22:58:55

US3012329

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:53:26

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:04:08
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered '0'	Jennifer Leyva (b) (4)	15 Sep 2020 22:58:55

US3012329

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 21:53:26

[Date of Informed Consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:04:08
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered '15 Sep 2020'	Jennifer Leyva (b) (4)	15 Sep 2020 22:59:36

US3012329

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 21:53:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:04:08
User entered 'Sep 2020'	System	15 Sep 2020 22:59:36

US3012329

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 21:53:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:04:08
User entered '2020'	System	15 Sep 2020 22:59:36

US3012329

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 21:53:26

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:04:08
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered 'Amendment 3 (3)'	Jennifer Leyva (b) (4)	15 Sep 2020 22:59:36

US3012329

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 21:53:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:04:08
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered 'Yes (Y)'	Jennifer Leyva (b) (4)	15 Sep 2020 22:59:36

US3012329

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 21:53:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:04:08
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered empty.	Jennifer Leyva (b) (4)	15 Sep 2020 22:59:36

US3012329

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 21:53:26

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:04:08
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered empty.	Jennifer Leyva (b) (4)	15 Sep 2020 22:59:36

US3012329

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 21:53:26

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:04:08
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered 'No (N)'	Jennifer Leyva (b) (4)	15 Sep 2020 22:59:36

US3012329

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 21:53:26

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:04:08
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	15 Sep 2020 20:39:26

US3012329

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 21:53:26

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:04:08
User entered 'I'	System	15 Sep 2020 22:59:40

US3012329

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 11 Aug 2021 21:53:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:04:08
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered 'Yes (Y)'	Jennifer Leyva (b) (4)	15 Sep 2020 22:59:40

US3012329

Folder: Screening

Form: Medical History Summary

Generated On: 11 Aug 2021 21:53:26

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:04:08
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered 'Yes (Y)'	Jennifer Leyva (b) (4)	17 Sep 2020 21:38:57

US3012329

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 21:53:26

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:04:08
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
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)	17 Sep 2020 21:40:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Sep 2020 21:40:43
Data point term sent to Coder	System	17 Sep 2020 21:39:52
User entered 'uterine fibroids'	Jennifer Leyva (b) (4)	17 Sep 2020 21:39:18

US3012329

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 21:53:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:04:08
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered 'UN UNK 1998'	Jennifer Leyva (b) (4)	17 Sep 2020 21:39:18

US3012329

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 21:53:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:04:08
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered '0'	Jennifer Leyva (b) (4)	17 Sep 2020 21:39:18

US3012329

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 21:53:26

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:04:08
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered 'No (N)'	Jennifer Leyva (b) (4)	17 Sep 2020 21:39:18

US3012329

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 21:53:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:04:08
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered 'UN UNK 1998'	Jennifer Leyva (b) (4)	17 Sep 2020 21:39:18

US3012329

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 21:53:26

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:04:08
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered '0'	Jennifer Leyva (b) (4)	17 Sep 2020 21:39:18

US3012329

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 21:53:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:04:08
User entered 'Jan 1998'	System	17 Sep 2020 21:39:18

US3012329

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 21:53:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:04:08
User entered '1998'	System	17 Sep 2020 21:39:18

US3012329

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 21:53:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:04:08
User entered 'Jan 1998'	System	17 Sep 2020 21:39:18

US3012329

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 21:53:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:04:08
User entered '1998'	System	17 Sep 2020 21:39:18

US3012329

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 21:53:26

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:04:08
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Uterine therapeutic procedures, PT: Hysterectomy, LLT: Hysterectomy - version MedDRA\\23.0.	Coder Import (b) (4)	17 Sep 2020 21:40:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Sep 2020 21:40:43
Data point term sent to Coder	System	17 Sep 2020 21:39:52
User entered 'hysterectomy'	Jennifer Leyva (b) (4)	17 Sep 2020 21:39:26

US3012329

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 21:53:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:04:08
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered 'UN UNK 1998'	Jennifer Leyva (b) (4)	17 Sep 2020 21:39:26

US3012329

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 21:53:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:04:08
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered '0'	Jennifer Leyva (b) (4)	17 Sep 2020 21:39:26

US3012329

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 21:53:26

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:04:08
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User closed query 'Per DM CLR: Ongoing is marked for a surgical procedure. Please review and confirm to add a stop date as surgical procedures are not expected to remain ongoing. Note, procedures/surgeries typically have the same start/stop date. Please correct dates or provide explanation for the Med History duration. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	14 Oct 2020 19:30:35
Query 'Per DM CLR: Ongoing is marked for a surgical procedure. Please review and confirm to add a stop date as surgical procedures are not expected to remain ongoing. Note, procedures/surgeries typically have the same start/stop date. Please correct dates or provide explanation for the Med History duration. Update eCRF as appropriate. ' answered with 'DATA UPDATED' (Site from DM).	Lamar Box (b) (4)	08 Oct 2020 21:21:06
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	08 Oct 2020 21:20:55
User opened query 'Per DM CLR: Ongoing is marked for a surgical procedure. Please review and confirm to add a stop date as surgical procedures are not expected to remain ongoing. Note, procedures/surgeries typically have the same start/stop date. Please correct dates or provide explanation for the Med History duration. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 16:42:30
User entered 'Yes (Y)'	Jennifer Leyva (b) (4)	17 Sep 2020 21:39:26

US3012329

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 21:53:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:04:08
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered 'UN UNK 1998' reason for change:	(b) (4)	
Data Entry Error	Lamar Box (b) (4)	08 Oct 2020 21:20:55
User entered empty.	(b) (4)	
	Jennifer Leyva (b) (4)	17 Sep 2020 21:39:26
	(b) (4)	

US3012329

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 21:53:26

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:04:08
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered '0'	Jennifer Leyva (b) (4)	17 Sep 2020 21:39:26

US3012329

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 21:53:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:04:08
User entered 'Jan 1998'	System	17 Sep 2020 21:39:26

US3012329

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 21:53:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:04:08
User entered '1998'	System	17 Sep 2020 21:39:26

US3012329

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 21:53:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:04:08
User entered 'Jan 1998'	System	08 Oct 2020 21:20:55
User entered empty.	System	17 Sep 2020 21:39:26

US3012329

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 21:53:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:04:08
User entered '1998'	System	08 Oct 2020 21:20:55
User entered empty.	System	17 Sep 2020 21:39:26

US3012329

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 21:53:26

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:04:08
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User coded data point as SOC: Social circumstances, HLT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\\23.0.	Coder Import (b) (4)	17 Sep 2020 21:40:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Sep 2020 21:40:43
Data point term sent to Coder	System	17 Sep 2020 21:39:52
User entered 'postmenopausal'	Jennifer Leyva (b) (4)	17 Sep 2020 21:39:40

US3012329

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 21:53:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:04:08
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered 'UN UNK 1999'	Jennifer Leyva (b) (4)	17 Sep 2020 21:39:40

US3012329

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 21:53:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:04:08
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered '0'	Jennifer Leyva (b) (4)	17 Sep 2020 21:39:40

US3012329

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 21:53:26

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:04:08
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered 'Yes (Y)'	Jennifer Leyva (b) (4)	17 Sep 2020 21:39:40

US3012329

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 21:53:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:04:08
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered empty.	Jennifer Leyva (b) (4)	17 Sep 2020 21:39:40

US3012329

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 21:53:26

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:04:08
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered '0'	Jennifer Leyva (b) (4)	17 Sep 2020 21:39:40

US3012329

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 21:53:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:04:08
User entered 'Jan 1999'	System	17 Sep 2020 21:39:40

US3012329

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 21:53:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:04:08
User entered '1999'	System	17 Sep 2020 21:39:40

US3012329

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 21:53:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:04:08
User entered empty.	System	17 Sep 2020 21:39:40

US3012329

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 21:53:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:04:08
User entered empty.	System	17 Sep 2020 21:39:40

US3012329

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:53:26

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:04:08
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered 'Yes (Y)'	Jennifer Leyva (b) (4)	17 Sep 2020 21:40:18

US3012329

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:53:26

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:04:08
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User closed query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	17 Sep 2020 21:40:23
Query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' answered by data change (Site from System).	System	17 Sep 2020 21:40:23
User entered '15 Sep 2020' reason for change: Data Entry Error	Jennifer Leyva (b) (4)	17 Sep 2020 21:40:23
User opened query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	17 Sep 2020 21:40:18
User entered '17 Sep 2020'	Jennifer Leyva (b) (4)	17 Sep 2020 21:40:18

US3012329

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:53:26

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:04:08
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered '15:54'	Jennifer Leyva (b) (4)	17 Sep 2020 21:40:18

US3012329

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:53:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:04:08
User entered '15 Sep 2020 15:54'	System	17 Sep 2020 21:40:23
User entered '17 Sep 2020 15:54'	System	17 Sep 2020 21:40:18

US3012329

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:53:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:04:08
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered '63.0' in	(b) (4) Jennifer Leyva (b) (4)	17 Sep 2020 21:40:18
DataPoint set to visible.	(b) (4) System	15 Sep 2020 22:59:40

US3012329

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:53:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:04:08
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered '155.8' lb	(b) (4) Jennifer Leyva (b) (4)	17 Sep 2020 21:40:18
DataPoint set to visible.	(b) (4) System	15 Sep 2020 22:59:40

US3012329

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:53:26

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:04:08
User entered '27.65644'	System	17 Sep 2020 21:40:18
DataPoint set to visible.	System	15 Sep 2020 22:59:40

US3012329

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:53:26

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:04:08
User entered 'kg/m2'	System	17 Sep 2020 21:40:18
DataPoint set to visible.	System	15 Sep 2020 22:59:40

US3012329

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:53:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:04:08
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered missing code ND - Not Done.	Jennifer Leyva (b) (4)	17 Sep 2020 21:40:18

US3012329

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:53:26

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:04:08
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered empty.	Jennifer Leyva (b) (4)	17 Sep 2020 21:40:18

US3012329

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:53:26

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:04:08
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered empty.	Jennifer Leyva (b) (4)	17 Sep 2020 21:40:18

US3012329

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:53:26

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:04:08
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered missing code ND - Not Done.	Jennifer Leyva (b) (4)	17 Sep 2020 21:40:18

US3012329

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:53:26

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:04:08
User entered 'bpm'	System	17 Sep 2020 21:40:18

US3012329

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:53:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:04:08
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered missing code ND - Not Done.	Jennifer Leyva (b) (4)	17 Sep 2020 21:40:18

US3012329

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:53:26

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:04:08
User entered 'breaths/min'	System	17 Sep 2020 21:40:18

US3012329

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:53:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:04:08
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered missing code ND - Not Done.	Jennifer Leyva (b) (4)	17 Sep 2020 21:40:18

US3012329

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:53:26

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:04:08
User entered 'mmHg'	System	17 Sep 2020 21:40:18

US3012329

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:53:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:04:08
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered missing code ND - Not Done.	Jennifer Leyva (b) (4)	17 Sep 2020 21:40:18

US3012329

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:53:26

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:04:08
User entered 'mmHg'	System	17 Sep 2020 21:40:18

US3012329

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:53:26

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:04:08

US3012329

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:53:26

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:04:08

US3012329

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 21:53:26

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:04:08
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered 'Yes (Y)'	Jennifer Leyva (b) (4)	17 Sep 2020 21:40:34

US3012329

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 21:53:26

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:04:08
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered '15 Sep 2020'	Jennifer Leyva (b) (4)	17 Sep 2020 21:40:34

US3012329

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 21:53:26

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:04:08
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered '15 Sep 2020'	Jennifer Leyva (b) (4)	17 Sep 2020 21:40:51

US3012329

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 21:53:26

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:04:08
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered 'No (N)'	Jennifer Leyva (b) (4)	17 Sep 2020 21:40:51

US3012329

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 21:53:26

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:04:08
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered 'Surgically sterile (SURGICALLY STERILE)'	Jennifer Leyva (b) (4)	17 Sep 2020 21:40:51

US3012329

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 21:53:26

[If Partner medically sterile or Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:04:08
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered empty.	Jennifer Leyva (b) (4)	17 Sep 2020 21:40:51

US3012329

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 21:53:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:04:08
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered 'UN UNK 1998'	Jennifer Leyva (b) (4)	17 Sep 2020 21:40:51

US3012329

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 21:53:26

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:04:08
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered '0'	Jennifer Leyva (b) (4)	17 Sep 2020 21:40:51

US3012329

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 21:53:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:04:08
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered empty.	Jennifer Leyva (b) (4)	17 Sep 2020 21:40:51

US3012329

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 21:53:26

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:04:08
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered '0'	Jennifer Leyva (b) (4)	17 Sep 2020 21:40:51

US3012329

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:53:26

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 12:04:08
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered 'No (N)'	Jennifer Leyva (b) (4)	17 Sep 2020 21:41:24

US3012329

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:53:26

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 12:04:08
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered 'No (N)'	Jennifer Leyva (b) (4)	17 Sep 2020 21:41:24

US3012329

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:53:26

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 12:04:08
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered 'No (N)'	Jennifer Leyva (b) (4)	17 Sep 2020 21:41:24

US3012329

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:53:26

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 12:04:08
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered 'No (N)'	Jennifer Leyva (b) (4)	17 Sep 2020 21:41:24

US3012329

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:53:26

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 12:04:08
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered 'No (N)'	Jennifer Leyva (b) (4)	17 Sep 2020 21:41:24

US3012329

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:53:26

[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 12:04:08
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered 'Yes (Y)'	Jennifer Leyva (b) (4)	17 Sep 2020 21:41:24

US3012329

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:53:26

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 12:04:08
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered 'No (N)'	Jennifer Leyva (b) (4)	17 Sep 2020 21:41:24

US3012329

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:53:26

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 12:04:08
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered 'No (N)'	Jennifer Leyva (b) (4)	17 Sep 2020 21:41:24

US3012329

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:53:26

[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 12:04:08
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered 'No (N)'	Jennifer Leyva (b) (4)	17 Sep 2020 21:41:24

US3012329

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:53:26

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 12:04:08
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered 'No (N)'	Jennifer Leyva (b) (4)	17 Sep 2020 21:41:24

US3012329

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:53:26

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 12:04:08
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered 'No (N)'	Jennifer Leyva (b) (4)	17 Sep 2020 21:41:24

US3012329

Folder: Screening

Form: Risk of Exposure

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Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:04:08
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered 'No (N)'	Jennifer Leyva (b) (4)	17 Sep 2020 21:41:24

US3012329

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:53:26

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:04:08
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered empty.	Jennifer Leyva (b) (4)	17 Sep 2020 21:41:24

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Folder: Screening

Form: Risk of Exposure

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No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:04:08
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered '0'	Jennifer Leyva (b) (4)	17 Sep 2020 21:41:24

US3012329

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:53:26

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:04:08
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered '0'	Jennifer Leyva (b) (4)	17 Sep 2020 21:41:24

US3012329

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:53:26

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 12:04:08
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered '0'	Jennifer Leyva (b) (4)	17 Sep 2020 21:41:24

US3012329

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:53:26

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 12:04:08
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered '0'	Jennifer Leyva (b) (4)	17 Sep 2020 21:41:24

US3012329

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:53:26

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 12:04:08
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered '0'	Jennifer Leyva (b) (4)	17 Sep 2020 21:41:24

US3012329

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:53:26

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:04:08
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered 'I'	Jennifer Leyva (b) (4)	17 Sep 2020 21:41:24

US3012329

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:53:26

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:04:08
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered '0'	Jennifer Leyva (b) (4)	17 Sep 2020 21:41:24

US3012329

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:53:26

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:04:08
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered empty.	Jennifer Leyva (b) (4)	17 Sep 2020 21:41:24

US3012329

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 21:53:26

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered 'Yes (Y)'	Jennifer Leyva (b) (4)	17 Sep 2020 21:41:34

US3012329

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 21:53:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered '15 Sep 2020'	Jennifer Leyva (b) (4)	17 Sep 2020 21:41:34

US3012329

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 21:53:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered 'Clinic (Clinic)'	Jennifer Leyva (b) (4)	17 Sep 2020 21:41:34

US3012329

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 21:53:26

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User entered 'VISIT1'	System	17 Sep 2020 21:41:34

US3012329

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:53:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered '15 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	15 Sep 2020 22:09:17

US3012329

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:53:26

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered '114216'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	15 Sep 2020 22:09:17

US3012329

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:53:26

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	15 Sep 2020 22:09:17

US3012329

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:53:26

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)	27 Mar 2021 17:32:06
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered 'No (N)'	Jennifer Leyva (b) (4)	17 Sep 2020 21:41:48

US3012329

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:53:26

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)	27 Mar 2021 17:32:06
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered 'No (N)'	Jennifer Leyva (b) (4)	17 Sep 2020 21:41:48

US3012329

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:53:26

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered 'No (N)'	Jennifer Leyva (b) (4)	17 Sep 2020 21:41:48

US3012329

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:53:26

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered 'No (N)'	Jennifer Leyva (b) (4)	17 Sep 2020 21:41:48

US3012329

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:53:26

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered 'No (N)'	Jennifer Leyva (b) (4)	17 Sep 2020 21:41:48

US3012329

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:53:26

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User closed query 'Per CDM: This field requires yes or no. Please complete. ' (Site from DM).	(b) (4)	30 Oct 2020 08:30:56
Query 'Per CDM: This field requires yes or no. Please complete. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 08:30:56
Query 'Per CDM: This field requires yes or no. Please complete. ' answered with 'updated' (Site from DM).	Pamela Fidler (b) (4)	28 Oct 2020 16:03:40
User entered 'No (N)'	Pamela Fidler (b) (4)	28 Oct 2020 16:03:37
User opened query 'Per CDM: This field requires yes or no. Please complete. ' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 16:00:39
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 09:18:05
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 09:18:04

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:53:26

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered missing code ND - Not Done.	Jennifer Leyva (b) (4)	17 Sep 2020 21:42:15

US3012329

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:53:26

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered missing code ND - Not Done.	Jennifer Leyva (b) (4)	17 Sep 2020 21:42:15

US3012329

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:53:26

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered missing code ND - Not Done.	Jennifer Leyva (b) (4)	17 Sep 2020 21:42:15

US3012329

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:53:26

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered missing code ND - Not Done.	Jennifer Leyva (b) (4)	17 Sep 2020 21:42:15

US3012329

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:53:26

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User accepted default value 'Pre-Dose (PREDOSE)'	Jennifer Leyva (b) (4) (b) (4)	17 Sep 2020 21:42:15

US3012329

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:53:26

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered 'Yes (Y)'	Jennifer Leyva (b) (4)	17 Sep 2020 21:42:15

US3012329

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:53:26

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered '15 Sep 2020'	Jennifer Leyva (b) (4)	17 Sep 2020 21:42:15

US3012329

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:53:26

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered '15:54'	Jennifer Leyva (b) (4)	17 Sep 2020 21:42:15

US3012329

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:53:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User entered '15 Sep 2020 15:54'	System	17 Sep 2020 21:42:15

US3012329

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:53:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered '98.4' F	Jennifer Leyva (b) (4)	17 Sep 2020 21:42:15

US3012329

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:53:26

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered 'Oral (Oral)'	Jennifer Leyva (b) (4)	17 Sep 2020 21:42:15

US3012329

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:53:26

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered empty.	Jennifer Leyva (b) (4)	17 Sep 2020 21:42:15

US3012329

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:53:26

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered '78'	Jennifer Leyva (b) (4)	17 Sep 2020 21:42:15

US3012329

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:53:26

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User entered 'bpm'	System	17 Sep 2020 21:42:15

US3012329

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:53:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered '14'	Jennifer Leyva (b) (4)	17 Sep 2020 21:42:15

US3012329

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:53:26

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User entered 'breaths/min'	System	17 Sep 2020 21:42:15

US3012329

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:53:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered '126'	Jennifer Leyva (b) (4)	17 Sep 2020 21:42:15

US3012329

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:53:26

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User entered 'mmHg'	System	17 Sep 2020 21:42:15

US3012329

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:53:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered '84'	Jennifer Leyva (b) (4)	17 Sep 2020 21:42:15

US3012329

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:53:26

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User entered 'mmHg'	System	17 Sep 2020 21:42:15

US3012329

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:53:26

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered missing code ND - Not Done.	Jennifer Leyva (b) (4)	17 Sep 2020 21:42:15

US3012329

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:53:26

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered missing code ND - Not Done.	Jennifer Leyva (b) (4)	17 Sep 2020 21:42:15

US3012329

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:53:26

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User accepted default value 'Post-Dose (POSTDOSE)'	Jennifer Leyva (b) (4) (b) (4)	17 Sep 2020 21:42:40

US3012329

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:53:26

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered 'Yes (Y)'	Jennifer Leyva (b) (4)	17 Sep 2020 21:42:40

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:53:26

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered '15 Sep 2020'	Jennifer Leyva (b) (4)	17 Sep 2020 21:42:40

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:53:26

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered '18:12'	Jennifer Leyva (b) (4)	17 Sep 2020 21:42:40

US3012329

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:53:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User entered '15 Sep 2020 18:12'	System	17 Sep 2020 21:42:40

US3012329

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:53:26

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered '98.6' F	Jennifer Leyva (b) (4)	17 Sep 2020 21:42:40

US3012329

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:53:26

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered 'Oral (Oral)'	Jennifer Leyva (b) (4)	17 Sep 2020 21:42:40

US3012329

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:53:26

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered empty.	Jennifer Leyva (b) (4)	17 Sep 2020 21:42:40

US3012329

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:53:26

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered '68'	Jennifer Leyva (b) (4)	17 Sep 2020 21:42:40

US3012329

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:53:26

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User entered 'bpm'	System	17 Sep 2020 21:42:40

US3012329

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:53:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered '14'	Jennifer Leyva (b) (4)	17 Sep 2020 21:42:40

US3012329

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:53:26

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User entered 'breaths/min'	System	17 Sep 2020 21:42:40

US3012329

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:53:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered '121'	Jennifer Leyva (b) (4)	17 Sep 2020 21:42:40

US3012329

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:53:26

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User entered 'mmHg'	System	17 Sep 2020 21:42:40

US3012329

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:53:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered '81'	Jennifer Leyva (b) (4)	17 Sep 2020 21:42:40

US3012329

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:53:26

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User entered 'mmHg'	System	17 Sep 2020 21:42:40

US3012329

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 21:53:26

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered 'No (N)'	Jennifer Leyva (b) (4)	17 Sep 2020 21:42:45

US3012329

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 21:53:26

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered empty.	Jennifer Leyva (b) (4)	17 Sep 2020 21:42:45

US3012329

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:53:26

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered 'Yes (Y)'	Jennifer Leyva (b) (4)	15 Sep 2020 23:01:23

US3012329

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:53:26

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered empty.	Jennifer Leyva (b) (4)	15 Sep 2020 23:01:23

US3012329

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:53:26

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)	27 Mar 2021 17:32:06
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered empty.	Jennifer Leyva (b) (4)	15 Sep 2020 23:01:23

US3012329

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:53:26

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User entered 'MRNA-1273 OR PLACEBO'	System	15 Sep 2020 23:01:23

US3012329

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:53:26

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered '15 Sep 2020'	Jennifer Leyva (b) (4)	15 Sep 2020 23:01:23

US3012329

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:53:26

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered '17:19'	Jennifer Leyva (b) (4)	15 Sep 2020 23:01:23

US3012329

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:53:26

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User entered '15 Sep 2020 17:19'	System	15 Sep 2020 23:01:23

US3012329

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:53:26

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered 'Left Arm (LEFT ARM)'	Jennifer Leyva (b) (4)	15 Sep 2020 23:01:23

US3012329

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:53:26

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User entered 'ONCE'	System	15 Sep 2020 23:01:23

US3012329

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:53:26

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User entered 'INTRAMUSCULAR'	System	15 Sep 2020 23:01:23

US3012329

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:53:26

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered 'Yes (Y)'	Jennifer Leyva (b) (4)	17 Sep 2020 21:43:10

US3012329

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:53:26

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 15SEP2020 is recorded under Visit 1 Day 1 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you.' (Site from DM).	(b) (4)	
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 15SEP2020 is recorded under Visit 1 Day 1 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you.' answered with 'Unscheduled kit used. Sample is for V1 Day 1, visit on 15SEP2020' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 18:20:47
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 15SEP2020 is recorded under Visit 1 Day 1 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you.' (Site from DM).	Jennifer Leyva (b) (4)	20 Oct 2020 14:09:10
User entered '15 Sep 2020'	(b) (4)	
	(b) (4), (b) (6)	19 Oct 2020 07:38:43
	Jennifer Leyva (b) (4)	17 Sep 2020 21:43:10
	(b) (4)	

US3012329

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:53:26

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered '16:55'	Jennifer Leyva (b) (4)	17 Sep 2020 21:43:10

US3012329

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:53:26

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User entered '15 Sep 2020 16:55'	System	17 Sep 2020 21:43:10

US3012329

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 21:53:26

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User closed query 'Per GCL Lab Recon: it appears GCL has this as an Unscheduled Visit. Please review and confirm 15SEP2020 is for Day 1 or clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Nov 2020 18:28:47
Query 'Per GCL Lab Recon: it appears GCL has this as an Unscheduled Visit. Please review and confirm 15SEP2020 is for Day 1 or clarify. ' answered with 'Unscheduled lab kit was used but sample is for Day 1 visit, 15SEP2020' (Site from DM).	Jennifer Leyva (b) (4) (b) (4)	20 Oct 2020 13:49:59
User opened query 'Per GCL Lab Recon: it appears GCL has this as an Unscheduled Visit. Please review and confirm 15SEP2020 is for Day 1 or clarify. ' (Site from DM).	(b) (4), (b) (6)	18 Oct 2020 16:53:44
User entered '15 Sep 2020'	Jennifer Leyva (b) (4) (b) (4)	17 Sep 2020 21:43:23

US3012329

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 21:53:26

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Jennifer Leyva (b) (4) (b) (4)	17 Sep 2020 21:43:23

US3012329

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 21:53:26

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered 'Yes (Y)'	Jennifer Leyva (b) (4)	17 Sep 2020 21:43:23

US3012329

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 21:53:26

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered '16:23'	Jennifer Leyva (b) (4)	17 Sep 2020 21:43:23

US3012329

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 21:53:26

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User entered '15 Sep 2020 16:23'	System	17 Sep 2020 21:43:23

US3012329

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 21:53:26

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Jennifer Leyva (b) (4) (b) (4)	17 Sep 2020 21:43:23

US3012329

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 21:53:26

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered 'No (N)'	Jennifer Leyva (b) (4)	17 Sep 2020 21:43:23

US3012329

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 21:53:26

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered empty.	Jennifer Leyva (b) (4)	17 Sep 2020 21:43:23

US3012329

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 21:53:26

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User entered empty.	System	17 Sep 2020 21:43:23

US3012329

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 21:53:26

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered 'Yes (Y)'	Jennifer Leyva (b) (4)	17 Sep 2020 21:43:26

US3012329

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 21:53:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User entered 'I'	System	17 Sep 2020 21:43:26

US3012329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
Data entry locked.	System	15 Sep 2020 23:01:23
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	15 Sep 2020 23:01:23

US3012329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 21:53:26

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-09-15T18:03:47', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '704671b4-c7ac-4db5-b056-a2912c320a7b' User entered 'Yes (Y)'	System	15 Sep 2020 23:04:39
	System	15 Sep 2020 23:04:39

US3012329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 21:53:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-09-15T18:03:59', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '704671b4-c7ac-4db5-b056-a2912c320a7b' User entered '98.6'	System	15 Sep 2020 23:04:39
	System	15 Sep 2020 23:04:39

US3012329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 21:53:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-09-15T18:04:12', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '704671b4-c7ac-4db5-b056-a2912c320a7b' User entered 'No (N)'	System	15 Sep 2020 23:04:39
	System	15 Sep 2020 23:04:39

US3012329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 21:53:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-09-15T18:04:32', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '704671b4-c7ac-4db5-b056-a2912c320a7b' User entered '15 Sep 2020 18:04'	System	15 Sep 2020 23:04:39
	System	15 Sep 2020 23:04:39

US3012329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 21:53:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
User entered '15 Sep 2020 17:39'	System	15 Sep 2020 23:01:23

US3012329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 21:53:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
User entered '15 Sep 2020 20:09'	System	15 Sep 2020 23:01:23

US3012329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
Data entry locked.	System	15 Sep 2020 23:01:23
User entered 'Day 1, after vaccination (at home)'	System	15 Sep 2020 23:01:23

US3012329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 21:53:26

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-09-15T21:37:43', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '58c16956-79dc-4212-8cbb-73dac9c36969' User entered 'Yes (Y)'	System	16 Sep 2020 02:38:22
	System	16 Sep 2020 02:38:22

US3012329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 21:53:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-09-15T21:37:54', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '58c16956-79dc-4212-8cbb-73dac9c36969' User entered '98.6'	System	16 Sep 2020 02:38:22
	System	16 Sep 2020 02:38:22

US3012329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 21:53:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-09-15T21:38:04', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '58c16956-79dc-4212-8cbb-73dac9c36969'	System	16 Sep 2020 02:38:22
User entered 'No (N)'	System	16 Sep 2020 02:38:22

US3012329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 21:53:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-09-15T21:38:19', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '58c16956-79dc-4212-8cbb-73dac9c36969' User entered '15 Sep 2020 21:38'	System	16 Sep 2020 02:38:22
	System	16 Sep 2020 02:38:22

US3012329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 21:53:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
User entered '15 Sep 2020 21:04'	System	15 Sep 2020 23:01:23

US3012329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 21:53:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
User entered '16 Sep 2020 11:59'	System	15 Sep 2020 23:01:23

US3012329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
Data entry locked.	System	15 Sep 2020 23:01:23
User entered 'Day 2'	System	15 Sep 2020 23:01:23

US3012329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 21:53:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-09-16T12:49:16', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: 'b854fc4b-9811-450a-884a-da4b36dbb84e' User entered 'Yes (Y)'	System	16 Sep 2020 17:49:41
	System	16 Sep 2020 17:49:41

US3012329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 21:53:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-09-16T12:49:23', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: 'b854fc4b-9811-450a-884a-da4b36dbb84e' User entered '98.6'	System	16 Sep 2020 17:49:41
	System	16 Sep 2020 17:49:41

US3012329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 21:53:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-09-16T12:49:29', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: 'b854fc4b-9811-450a-884a-da4b36dbb84e' User entered 'No (N)'	System	16 Sep 2020 17:49:41
	System	16 Sep 2020 17:49:41

US3012329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 21:53:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-09-16T12:49:36', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: 'b854fc4b-9811-450a-884a-da4b36dbb84e' User entered '16 Sep 2020 12:49'	System	16 Sep 2020 17:49:41
	System	16 Sep 2020 17:49:41

US3012329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 21:53:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
User entered '16 Sep 2020 12:00'	System	15 Sep 2020 23:01:23

US3012329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 21:53:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
User entered '17 Sep 2020 11:59'	System	15 Sep 2020 23:01:23

US3012329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
Data entry locked.	System	15 Sep 2020 23:01:23
User entered 'Day 3'	System	15 Sep 2020 23:01:23

US3012329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 21:53:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-09-17T12:00:50', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: 'c0bfd182-e855-4be0-b5b3-486f99a532cb' User entered 'Yes (Y)'	System	17 Sep 2020 17:02:28
	System	17 Sep 2020 17:02:28

US3012329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 21:53:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-09-17T12:01:04', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: 'c0bfd182-e855-4be0-b5b3-486f99a532cb' User entered '97.8'	System	17 Sep 2020 17:02:28
	System	17 Sep 2020 17:02:28

US3012329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 21:53:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-09-17T12:01:08', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: 'c0bfd182-e855-4be0-b5b3-486f99a532cb' User entered 'No (N)'	System	17 Sep 2020 17:02:28
	System	17 Sep 2020 17:02:28

US3012329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 21:53:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-09-17T12:01:15', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: 'c0bfd182-e855-4be0-b5b3-486f99a532cb' User entered '17 Sep 2020 12:01'	System	17 Sep 2020 17:02:28
	System	17 Sep 2020 17:02:28

US3012329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 21:53:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
User entered '17 Sep 2020 12:00'	System	15 Sep 2020 23:01:23

US3012329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 21:53:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
User entered '18 Sep 2020 11:59'	System	15 Sep 2020 23:01:23

US3012329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
Data entry locked.	System	15 Sep 2020 23:01:23
User entered 'Day 4'	System	15 Sep 2020 23:01:23

US3012329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 21:53:26

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-09-18T14:38:31', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '552887e5-2060-46a8-9b73-2c0f690ff2fa' User entered 'Yes (Y)'	System	18 Sep 2020 19:38:51
	System	18 Sep 2020 19:38:51

US3012329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 21:53:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-09-18T14:38:37', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '552887e5-2060-46a8-9b73-2c0f690ff2fa' User entered '98.6'	System	18 Sep 2020 19:38:51
	System	18 Sep 2020 19:38:51

US3012329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 21:53:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-09-18T14:38:43', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '552887e5-2060-46a8-9b73-2c0f690ff2fa' User entered 'No (N)'	System	18 Sep 2020 19:38:51
	System	18 Sep 2020 19:38:51

US3012329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 21:53:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-09-18T14:38:49', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '552887e5-2060-46a8-9b73-2c0f690ff2fa' User entered '18 Sep 2020 14:38'	System	18 Sep 2020 19:38:51
	System	18 Sep 2020 19:38:51

US3012329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 21:53:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
User entered '18 Sep 2020 12:00'	System	15 Sep 2020 23:01:23

US3012329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 21:53:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
User entered '19 Sep 2020 11:59'	System	15 Sep 2020 23:01:23

US3012329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
Data entry locked.	System	15 Sep 2020 23:01:23
User entered 'Day 5'	System	15 Sep 2020 23:01:23

US3012329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 21:53:26

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-09-19T13:10:44', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '69f5cab3-5ab9-453f-80ef-a2db92856cb9' User entered 'Yes (Y)'	System	19 Sep 2020 18:11:05
	System	19 Sep 2020 18:11:05

US3012329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 21:53:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-09-19T13:10:55', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '69f5cab3-5ab9-453f-80ef-a2db92856cb9' User entered '97.6'	System	19 Sep 2020 18:11:05
	System	19 Sep 2020 18:11:05

US3012329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 21:53:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-09-19T13:10:59', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '69f5cab3-5ab9-453f-80ef-a2db92856cb9' User entered 'No (N)'	System	19 Sep 2020 18:11:05
	System	19 Sep 2020 18:11:05

US3012329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 21:53:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-09-19T13:11:02', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '69f5cab3-5ab9-453f-80ef-a2db92856cb9' User entered '19 Sep 2020 13:11'	System	19 Sep 2020 18:11:05
	System	19 Sep 2020 18:11:05

US3012329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 21:53:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
User entered '19 Sep 2020 12:00'	System	15 Sep 2020 23:01:23

US3012329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 21:53:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
User entered '20 Sep 2020 11:59'	System	15 Sep 2020 23:01:23

US3012329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
Data entry locked.	System	15 Sep 2020 23:01:23
User entered 'Day 6'	System	15 Sep 2020 23:01:23

US3012329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 21:53:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-09-20T12:00:22', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '1588812a-a60b-4ce9-b5be-598336bfcaf3' User entered 'Yes (Y)'	System	20 Sep 2020 17:00:55
	System	20 Sep 2020 17:00:55

US3012329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 21:53:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-09-20T12:00:26', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '1588812a-a60b-4ce9-b5be-598336bfcaf3' User entered '98.6'	System	20 Sep 2020 17:00:55
	System	20 Sep 2020 17:00:55

US3012329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 21:53:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-09-20T12:00:47', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '1588812a-a60b-4ce9-b5be-598336bfcaf3' User entered 'No (N)'	System	20 Sep 2020 17:00:55
	System	20 Sep 2020 17:00:55

US3012329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 21:53:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-09-20T12:00:50', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '1588812a-a60b-4ce9-b5be-598336bfcaf3' User entered '20 Sep 2020 12:00'	System	20 Sep 2020 17:00:55
	System	20 Sep 2020 17:00:55

US3012329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 21:53:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
User entered '20 Sep 2020 12:00'	System	15 Sep 2020 23:01:23

US3012329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 21:53:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
User entered '21 Sep 2020 11:59'	System	15 Sep 2020 23:01:23

US3012329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
Data entry locked.	System	15 Sep 2020 23:01:23
User entered 'Day 7'	System	15 Sep 2020 23:01:23

US3012329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 21:53:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-09-21T12:00:52', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: 'abe22555-719c-4188-8a85-15fbddbfcf6a' User entered 'Yes (Y)'	System	21 Sep 2020 17:04:15
	System	21 Sep 2020 17:04:15

US3012329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 21:53:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-09-21T12:00:58', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: 'abe22555-719c-4188-8a85-15fbddbfcf6a' User entered '98.6'	System	21 Sep 2020 17:04:15
	System	21 Sep 2020 17:04:15

US3012329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 21:53:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-09-21T12:01:04', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: 'abe22555-719c-4188-8a85-15fbddbfcf6a' User entered 'No (N)'	System	21 Sep 2020 17:04:15
	System	21 Sep 2020 17:04:15

US3012329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 21:53:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-09-21T12:01:10', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: 'abe22555-719c-4188-8a85-15fbddbfcf6a' User entered '21 Sep 2020 12:01'	System	21 Sep 2020 17:04:15
	System	21 Sep 2020 17:04:15

US3012329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 21:53:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
User entered '21 Sep 2020 12:00'	System	15 Sep 2020 23:01:23

US3012329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 21:53:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
User entered '22 Sep 2020 11:59'	System	15 Sep 2020 23:01:23

US3012329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
Data entry locked.	System	15 Sep 2020 23:01:23
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	15 Sep 2020 23:01:23

US3012329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 21:53:26

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-09-15T18:04:52', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '98a2118f-9c76-4d5a-862d-98d02de6b70e' User entered 'None (1)'	System	15 Sep 2020 23:05:18
	System	15 Sep 2020 23:05:18

US3012329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 21:53:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-09-15T18:04:58', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '98a2118f-9c76-4d5a-862d-98d02de6b70e' User entered 'No (N)'	System	15 Sep 2020 23:05:18
	System	15 Sep 2020 23:05:18

US3012329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 21:53:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-09-15T18:05:03', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '98a2118f-9c76-4d5a-862d-98d02de6b70e' User entered 'No (N)'	System	15 Sep 2020 23:05:18
	System	15 Sep 2020 23:05:18

US3012329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 21:53:26

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-09-15T18:05:12', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '98a2118f-9c76-4d5a-862d-98d02de6b70e' User entered 'None (1)'	System	15 Sep 2020 23:05:18
	System	15 Sep 2020 23:05:18

US3012329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 21:53:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-09-15T18:05:16', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '98a2118f-9c76-4d5a-862d-98d02de6b70e' User entered '15 Sep 2020 18:05'	System	15 Sep 2020 23:05:18
	System	15 Sep 2020 23:05:18

US3012329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 21:53:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
User entered '15 Sep 2020 17:39'	System	15 Sep 2020 23:01:23

US3012329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 21:53:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
User entered '15 Sep 2020 20:09'	System	15 Sep 2020 23:01:23

US3012329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
Data entry locked.	System	15 Sep 2020 23:01:23
User entered 'Day 1, after vaccination (at home)'	System	15 Sep 2020 23:01:23

US3012329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 21:53:26

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-09-15T21:38:46', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '4fe1036a-760e-41c2-95dd-1a111d6d1e74' User entered 'None (1)'	System	16 Sep 2020 02:39:22
	System	16 Sep 2020 02:39:22

US3012329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 21:53:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-09-15T21:38:51', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '4fe1036a-760e-41c2-95dd-1a111d6d1e74' User entered 'No (N)'	System	16 Sep 2020 02:39:22
	System	16 Sep 2020 02:39:22

US3012329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 21:53:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-09-15T21:39:01', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '4fe1036a-760e-41c2-95dd-1a111d6d1e74' User entered 'No (N)'	System	16 Sep 2020 02:39:22
	System	16 Sep 2020 02:39:22

US3012329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 21:53:26

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-09-15T21:39:16', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '4fe1036a-760e-41c2-95dd-1a111d6d1e74'	System	16 Sep 2020 02:39:22
User entered 'None (1)'	System	16 Sep 2020 02:39:22

US3012329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 21:53:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-09-15T21:39:20', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '4fe1036a-760e-41c2-95dd-1a111d6d1e74' User entered '15 Sep 2020 21:39'	System	16 Sep 2020 02:39:22
	System	16 Sep 2020 02:39:22

US3012329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 21:53:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
User entered '15 Sep 2020 21:04'	System	15 Sep 2020 23:01:23

US3012329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 21:53:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
User entered '16 Sep 2020 11:59'	System	15 Sep 2020 23:01:23

US3012329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
Data entry locked.	System	15 Sep 2020 23:01:23
User entered 'Day 2'	System	15 Sep 2020 23:01:23

US3012329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 21:53:26

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-09-16T12:49:50', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '1512bf5a-cd47-4e6e-ba3a-d862c6ddf556'	System	16 Sep 2020 17:50:21
User entered 'None (1)'	System	16 Sep 2020 17:50:21

US3012329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 21:53:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-09-16T12:49:58', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '1512bf5a-cd47-4e6e-ba3a-d862c6ddf556'	System	16 Sep 2020 17:50:21
User entered 'No (N)'	System	16 Sep 2020 17:50:21

US3012329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 21:53:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-09-16T12:50:02', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '1512bf5a-cd47-4e6e-ba3a-d862c6ddf556'	System	16 Sep 2020 17:50:21
User entered 'No (N)'	System	16 Sep 2020 17:50:21

US3012329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 21:53:26

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-09-16T12:50:11', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '1512bf5a-cd47-4e6e-ba3a-d862c6ddf556'	System	16 Sep 2020 17:50:21
User entered 'None (1)'	System	16 Sep 2020 17:50:21

US3012329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 21:53:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-09-16T12:50:16', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '1512bf5a-cd47-4e6e-ba3a-d862c6ddf556' User entered '16 Sep 2020 12:50'	System	16 Sep 2020 17:50:21
	System	16 Sep 2020 17:50:21

US3012329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 21:53:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
User entered '16 Sep 2020 12:00'	System	15 Sep 2020 23:01:23

US3012329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 21:53:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
User entered '17 Sep 2020 11:59'	System	15 Sep 2020 23:01:23

US3012329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
Data entry locked.	System	15 Sep 2020 23:01:23
User entered 'Day 3'	System	15 Sep 2020 23:01:23

US3012329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 21:53:26

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-09-17T12:01:34', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '6829bbfc-3d7f-468f-8499-e73c788534d6'	System	17 Sep 2020 17:03:01
User entered 'None (1)'	System	17 Sep 2020 17:03:01

US3012329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 21:53:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-09-17T12:01:39', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '6829bbfc-3d7f-468f-8499-e73c788534d6' User entered 'No (N)'	System	17 Sep 2020 17:03:01
	System	17 Sep 2020 17:03:01

US3012329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 21:53:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-09-17T12:01:44', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '6829bbfc-3d7f-468f-8499-e73c788534d6' User entered 'No (N)'	System	17 Sep 2020 17:03:01
	System	17 Sep 2020 17:03:01

US3012329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 21:53:26

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-09-17T12:01:49', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '6829bbfc-3d7f-468f-8499-e73c788534d6'	System	17 Sep 2020 17:03:01
User entered 'None (1)'	System	17 Sep 2020 17:03:01

US3012329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 21:53:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-09-17T12:01:54', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '6829bbfc-3d7f-468f-8499-e73c788534d6' User entered '17 Sep 2020 12:01'	System	17 Sep 2020 17:03:01
	System	17 Sep 2020 17:03:01

US3012329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 21:53:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
User entered '17 Sep 2020 12:00'	System	15 Sep 2020 23:01:23

US3012329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 21:53:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
User entered '18 Sep 2020 11:59'	System	15 Sep 2020 23:01:23

US3012329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
Data entry locked.	System	15 Sep 2020 23:01:23
User entered 'Day 4'	System	15 Sep 2020 23:01:23

US3012329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 21:53:26

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-09-18T14:38:52', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: 'cc35806d-03ef-42e4-b91f-b50f1eb02b80'	System	18 Sep 2020 19:39:23
User entered 'None (1)'	System	18 Sep 2020 19:39:23

US3012329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 21:53:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-09-18T14:38:59', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: 'cc35806d-03ef-42e4-b91f-b50f1eb02b80'	System	18 Sep 2020 19:39:23
User entered 'No (N)'	System	18 Sep 2020 19:39:23

US3012329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 21:53:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-09-18T14:39:00', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: 'cc35806d-03ef-42e4-b91f-b50f1eb02b80' User entered 'No (N)'	System	18 Sep 2020 19:39:23
	System	18 Sep 2020 19:39:23

US3012329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 21:53:26

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-09-18T14:39:02', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: 'cc35806d-03ef-42e4-b91f-b50f1eb02b80'	System	18 Sep 2020 19:39:23
User entered 'None (1)'	System	18 Sep 2020 19:39:23

US3012329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 21:53:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-09-18T14:39:04', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: 'cc35806d-03ef-42e4-b91f-b50f1eb02b80' User entered '18 Sep 2020 14:39'	System	18 Sep 2020 19:39:23
	System	18 Sep 2020 19:39:23

US3012329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 21:53:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
User entered '18 Sep 2020 12:00'	System	15 Sep 2020 23:01:23

US3012329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 21:53:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
User entered '19 Sep 2020 11:59'	System	15 Sep 2020 23:01:23

US3012329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
Data entry locked.	System	15 Sep 2020 23:01:23
User entered 'Day 5'	System	15 Sep 2020 23:01:23

US3012329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 21:53:26

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-09-19T13:11:06', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '5304669b-7bcf-4f3b-96ff-b01328d8d542'	System	19 Sep 2020 18:11:22
User entered 'None (1)'	System	19 Sep 2020 18:11:22

US3012329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 21:53:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-09-19T13:11:09', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '5304669b-7bcf-4f3b-96ff-b01328d8d542'	System	19 Sep 2020 18:11:22
User entered 'No (N)'	System	19 Sep 2020 18:11:22

US3012329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 21:53:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-09-19T13:11:12', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '5304669b-7bcf-4f3b-96ff-b01328d8d542'	System	19 Sep 2020 18:11:22
User entered 'No (N)'	System	19 Sep 2020 18:11:22

US3012329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 21:53:26

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-09-19T13:11:14', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '5304669b-7bcf-4f3b-96ff-b01328d8d542'	System	19 Sep 2020 18:11:22
User entered 'None (1)'	System	19 Sep 2020 18:11:22

US3012329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 21:53:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-09-19T13:11:17', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '5304669b-7bcf-4f3b-96ff-b01328d8d542'	System	19 Sep 2020 18:11:22
User entered '19 Sep 2020 13:11'	System	19 Sep 2020 18:11:22

US3012329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 21:53:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
User entered '19 Sep 2020 12:00'	System	15 Sep 2020 23:01:23

US3012329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 21:53:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
User entered '20 Sep 2020 11:59'	System	15 Sep 2020 23:01:23

US3012329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
Data entry locked.	System	15 Sep 2020 23:01:23
User entered 'Day 6'	System	15 Sep 2020 23:01:23

US3012329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 21:53:26

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-09-20T12:00:54', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '0a7819f6-4648-4b98-a9f4-53dc870182f6' User entered 'None (1)'	System	20 Sep 2020 17:01:20
	System	20 Sep 2020 17:01:20

US3012329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 21:53:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-09-20T12:01:03', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '0a7819f6-4648-4b98-a9f4-53dc870182f6' User entered 'No (N)'	System	20 Sep 2020 17:01:20
	System	20 Sep 2020 17:01:20

US3012329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 21:53:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-09-20T12:01:06', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '0a7819f6-4648-4b98-a9f4-53dc870182f6' User entered 'No (N)'	System	20 Sep 2020 17:01:20
	System	20 Sep 2020 17:01:20

US3012329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 21:53:26

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-09-20T12:01:07', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '0a7819f6-4648-4b98-a9f4-53dc870182f6' User entered 'None (1)'	System	20 Sep 2020 17:01:20
	System	20 Sep 2020 17:01:20

US3012329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 21:53:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-09-20T12:01:10', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '0a7819f6-4648-4b98-a9f4-53dc870182f6' User entered '20 Sep 2020 12:01'	System	20 Sep 2020 17:01:20
	System	20 Sep 2020 17:01:20

US3012329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 21:53:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
User entered '20 Sep 2020 12:00'	System	15 Sep 2020 23:01:23

US3012329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 21:53:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
User entered '21 Sep 2020 11:59'	System	15 Sep 2020 23:01:23

US3012329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
Data entry locked.	System	15 Sep 2020 23:01:23
User entered 'Day 7'	System	15 Sep 2020 23:01:23

US3012329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 21:53:26

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-09-21T12:01:14', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '5c8ff78b-fc11-42ce-9cc6-a43e3e21b344' User entered 'None (1)'	System	21 Sep 2020 17:04:29
	System	21 Sep 2020 17:04:29

US3012329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 21:53:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-09-21T12:01:16', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '5c8ff78b-fc11-42ce-9cc6-a43e3e21b344' User entered 'No (N)'	System	21 Sep 2020 17:04:29
	System	21 Sep 2020 17:04:29

US3012329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 21:53:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-09-21T12:01:18', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '5c8ff78b-fc11-42ce-9cc6-a43e3e21b344' User entered 'No (N)'	System	21 Sep 2020 17:04:29
	System	21 Sep 2020 17:04:29

US3012329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 21:53:26

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-09-21T12:01:19', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '5c8ff78b-fc11-42ce-9cc6-a43e3e21b344' User entered 'None (1)'	System	21 Sep 2020 17:04:29
	System	21 Sep 2020 17:04:29

US3012329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 21:53:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-09-21T12:01:22', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '5c8ff78b-fc11-42ce-9cc6-a43e3e21b344' User entered '21 Sep 2020 12:01'	System	21 Sep 2020 17:04:29
	System	21 Sep 2020 17:04:29

US3012329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 21:53:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
User entered '21 Sep 2020 12:00'	System	15 Sep 2020 23:01:23

US3012329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 21:53:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
User entered '22 Sep 2020 11:59'	System	15 Sep 2020 23:01:23

US3012329

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
Data entry locked.	System	15 Sep 2020 23:01:23
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	15 Sep 2020 23:01:23

US3012329

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:53:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-09-15T18:05:26', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: 'f84e746a-77a5-48c5-9f57-49149312913d' User entered 'None (0)'	System	15 Sep 2020 23:06:16
	System	15 Sep 2020 23:06:16

US3012329

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:53:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-09-15T18:05:32', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: 'f84e746a-77a5-48c5-9f57-49149312913d' User entered 'None (0)'	System	15 Sep 2020 23:06:16
	System	15 Sep 2020 23:06:16

US3012329

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:53:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-09-15T18:05:37', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: 'f84e746a-77a5-48c5-9f57-49149312913d' User entered 'None (0)'	System	15 Sep 2020 23:06:16
	System	15 Sep 2020 23:06:16

US3012329

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:53:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-09-15T18:05:42', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: 'f84e746a-77a5-48c5-9f57-49149312913d' User entered 'None (0)'	System	15 Sep 2020 23:06:16
	System	15 Sep 2020 23:06:16

US3012329

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:53:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-09-15T18:05:46', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: 'f84e746a-77a5-48c5-9f57-49149312913d' User entered 'None (0)'	System	15 Sep 2020 23:06:16
	System	15 Sep 2020 23:06:16

US3012329

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:53:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-09-15T18:05:52', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: 'f84e746a-77a5-48c5-9f57-49149312913d' User entered 'None (0)'	System	15 Sep 2020 23:06:16
	System	15 Sep 2020 23:06:16

US3012329

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:53:26

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)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-09-15T18:06:09', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: 'f84e746a-77a5-48c5-9f57-49149312913d' User entered 'No (N)'	System	15 Sep 2020 23:06:16
	System	15 Sep 2020 23:06:16

US3012329

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:53:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-09-15T18:06:13', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: 'f84e746a-77a5-48c5-9f57-49149312913d' User entered '15 Sep 2020 18:06'	System	15 Sep 2020 23:06:16
	System	15 Sep 2020 23:06:16

US3012329

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:53:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
User entered '15 Sep 2020 17:39'	System	15 Sep 2020 23:01:23

US3012329

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:53:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
User entered '15 Sep 2020 20:09'	System	15 Sep 2020 23:01:23

US3012329

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
Data entry locked.	System	15 Sep 2020 23:01:23
User entered 'Day 1, after vaccination (at home)'	System	15 Sep 2020 23:01:23

US3012329

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:53:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-09-15T21:39:33', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '0529dd30-c8bd-4470-9bb3-1277cf834b4c' User entered 'None (0)'	System	16 Sep 2020 02:40:29
	System	16 Sep 2020 02:40:29

US3012329

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:53:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-09-15T21:39:40', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '0529dd30-c8bd-4470-9bb3-1277cf834b4c' User entered 'None (0)'	System	16 Sep 2020 02:40:29
	System	16 Sep 2020 02:40:29

US3012329

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:53:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-09-15T21:39:44', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '0529dd30-c8bd-4470-9bb3-1277cf834b4c' User entered 'None (0)'	System	16 Sep 2020 02:40:29
	System	16 Sep 2020 02:40:29

US3012329

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:53:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-09-15T21:40:09', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '0529dd30-c8bd-4470-9bb3-1277cf834b4c' User entered 'None (0)'	System	16 Sep 2020 02:40:29
	System	16 Sep 2020 02:40:29

US3012329

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:53:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-09-15T21:40:14', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '0529dd30-c8bd-4470-9bb3-1277cf834b4c' User entered 'None (0)'	System	16 Sep 2020 02:40:29
	System	16 Sep 2020 02:40:29

US3012329

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:53:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-09-15T21:40:17', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '0529dd30-c8bd-4470-9bb3-1277cf834b4c' User entered 'None (0)'	System	16 Sep 2020 02:40:29
	System	16 Sep 2020 02:40:29

US3012329

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:53:26

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)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-09-15T21:40:24', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '0529dd30-c8bd-4470-9bb3-1277cf834b4c' User entered 'No (N)'	System	16 Sep 2020 02:40:29
	System	16 Sep 2020 02:40:29

US3012329

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:53:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-09-15T21:40:27', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '0529dd30-c8bd-4470-9bb3-1277cf834b4c' User entered '15 Sep 2020 21:40'	System	16 Sep 2020 02:40:29
	System	16 Sep 2020 02:40:29

US3012329

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:53:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
User entered '15 Sep 2020 21:04'	System	15 Sep 2020 23:01:23

US3012329

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:53:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
User entered '16 Sep 2020 11:59'	System	15 Sep 2020 23:01:23

US3012329

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
Data entry locked.	System	15 Sep 2020 23:01:23
User entered 'Day 2'	System	15 Sep 2020 23:01:23

US3012329

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:53:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-09-16T12:50:25', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '7001adb1-e027-44d4-9560-4fde4ae12cd6' User entered 'None (0)'	System	16 Sep 2020 17:51:04
	System	16 Sep 2020 17:51:04

US3012329

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:53:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-09-16T12:50:29', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '7001adb1-e027-44d4-9560-4fde4ae12cd6' User entered 'None (0)'	System	16 Sep 2020 17:51:04
	System	16 Sep 2020 17:51:04

US3012329

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:53:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-09-16T12:50:35', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '7001adb1-e027-44d4-9560-4fde4ae12cd6' User entered 'None (0)'	System	16 Sep 2020 17:51:04
	System	16 Sep 2020 17:51:04

US3012329

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:53:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-09-16T12:50:41', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '7001adb1-e027-44d4-9560-4fde4ae12cd6' User entered 'None (0)'	System	16 Sep 2020 17:51:04
	System	16 Sep 2020 17:51:04

US3012329

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:53:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-09-16T12:50:44', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '7001adb1-e027-44d4-9560-4fde4ae12cd6' User entered 'None (0)'	System	16 Sep 2020 17:51:04
	System	16 Sep 2020 17:51:04

US3012329

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:53:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-09-16T12:50:53', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '7001adb1-e027-44d4-9560-4fde4ae12cd6' User entered 'None (0)'	System	16 Sep 2020 17:51:04
	System	16 Sep 2020 17:51:04

US3012329

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:53:26

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)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-09-16T12:50:57', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '7001adb1-e027-44d4-9560-4fde4ae12cd6' User entered 'No (N)'	System	16 Sep 2020 17:51:04
	System	16 Sep 2020 17:51:04

US3012329

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:53:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-09-16T12:51:01', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '7001adb1-e027-44d4-9560-4fde4ae12cd6' User entered '16 Sep 2020 12:51'	System	16 Sep 2020 17:51:04
	System	16 Sep 2020 17:51:04

US3012329

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:53:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
User entered '16 Sep 2020 12:00'	System	15 Sep 2020 23:01:23

US3012329

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:53:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
User entered '17 Sep 2020 11:59'	System	15 Sep 2020 23:01:23

US3012329

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
Data entry locked.	System	15 Sep 2020 23:01:23
User entered 'Day 3'	System	15 Sep 2020 23:01:23

US3012329

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:53:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-09-17T12:02:00', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '1c76a524-aca1-4913-9933-f9f4b3cd0e98' User entered 'None (0)'	System	17 Sep 2020 17:03:59
	System	17 Sep 2020 17:03:59

US3012329

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:53:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-09-17T12:02:03', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '1c76a524-aca1-4913-9933-f9f4b3cd0e98' User entered 'None (0)'	System	17 Sep 2020 17:03:59
	System	17 Sep 2020 17:03:59

US3012329

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:53:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-09-17T12:02:11', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '1c76a524-aca1-4913-9933-f9f4b3cd0e98' User entered 'None (0)'	System	17 Sep 2020 17:03:59
	System	17 Sep 2020 17:03:59

US3012329

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:53:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-09-17T12:02:20', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '1c76a524-aca1-4913-9933-f9f4b3cd0e98' User entered 'None (0)'	System	17 Sep 2020 17:03:59
	System	17 Sep 2020 17:03:59

US3012329

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:53:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-09-17T12:02:24', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '1c76a524-aca1-4913-9933-f9f4b3cd0e98' User entered 'None (0)'	System	17 Sep 2020 17:03:59
	System	17 Sep 2020 17:03:59

US3012329

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:53:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-09-17T12:02:35', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '1c76a524-aca1-4913-9933-f9f4b3cd0e98' User entered 'None (0)'	System	17 Sep 2020 17:03:59
	System	17 Sep 2020 17:03:59

US3012329

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:53:26

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)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-09-17T12:02:38', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '1c76a524-aca1-4913-9933-f9f4b3cd0e98'	System	17 Sep 2020 17:03:59
User entered 'No (N)'	System	17 Sep 2020 17:03:59

US3012329

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:53:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-09-17T12:02:41', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '1c76a524-aca1-4913-9933-f9f4b3cd0e98' User entered '17 Sep 2020 12:02'	System	17 Sep 2020 17:03:59
	System	17 Sep 2020 17:03:59

US3012329

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:53:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
User entered '17 Sep 2020 12:00'	System	15 Sep 2020 23:01:23

US3012329

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:53:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
User entered '18 Sep 2020 11:59'	System	15 Sep 2020 23:01:23

US3012329

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
Data entry locked.	System	15 Sep 2020 23:01:23
User entered 'Day 4'	System	15 Sep 2020 23:01:23

US3012329

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:53:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-09-18T14:39:08', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: 'c26761c9-46fe-4f59-99b9-4ebefc27433a' User entered 'None (0)'	System	18 Sep 2020 19:39:27
	System	18 Sep 2020 19:39:27

US3012329

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:53:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-09-18T14:39:09', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: 'c26761c9-46fe-4f59-99b9-4ebefc27433a' User entered 'None (0)'	System	18 Sep 2020 19:39:27
	System	18 Sep 2020 19:39:27

US3012329

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:53:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-09-18T14:39:11', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: 'c26761c9-46fe-4f59-99b9-4ebefc27433a' User entered 'None (0)'	System	18 Sep 2020 19:39:27
	System	18 Sep 2020 19:39:27

US3012329

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:53:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-09-18T14:39:15', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: 'c26761c9-46fe-4f59-99b9-4ebefc27433a' User entered 'None (0)'	System	18 Sep 2020 19:39:27
	System	18 Sep 2020 19:39:27

US3012329

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:53:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-09-18T14:39:17', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: 'c26761c9-46fe-4f59-99b9-4ebefc27433a' User entered 'None (0)'	System	18 Sep 2020 19:39:27
	System	18 Sep 2020 19:39:27

US3012329

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:53:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-09-18T14:39:18', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: 'c26761c9-46fe-4f59-99b9-4ebefc27433a' User entered 'None (0)'	System	18 Sep 2020 19:39:27
	System	18 Sep 2020 19:39:27

US3012329

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:53:26

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)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-09-18T14:39:20', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: 'c26761c9-46fe-4f59-99b9-4ebefc27433a' User entered 'No (N)'	System	18 Sep 2020 19:39:27
	System	18 Sep 2020 19:39:27

US3012329

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:53:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-09-18T14:39:22', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: 'c26761c9-46fe-4f59-99b9-4ebefc27433a' User entered '18 Sep 2020 14:39'	System	18 Sep 2020 19:39:27
	System	18 Sep 2020 19:39:27

US3012329

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:53:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
User entered '18 Sep 2020 12:00'	System	15 Sep 2020 23:01:23

US3012329

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:53:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
User entered '19 Sep 2020 11:59'	System	15 Sep 2020 23:01:23

US3012329

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
Data entry locked.	System	15 Sep 2020 23:01:23
User entered 'Day 5'	System	15 Sep 2020 23:01:23

US3012329

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:53:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-09-19T13:11:20', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '9d3f12e2-44a3-4086-8a72-a3f283688b2b' User entered 'None (0)'	System	19 Sep 2020 18:11:38
	System	19 Sep 2020 18:11:38

US3012329

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:53:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-09-19T13:11:22', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '9d3f12e2-44a3-4086-8a72-a3f283688b2b' User entered 'None (0)'	System	19 Sep 2020 18:11:38
	System	19 Sep 2020 18:11:38

US3012329

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:53:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-09-19T13:11:24', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '9d3f12e2-44a3-4086-8a72-a3f283688b2b' User entered 'None (0)'	System	19 Sep 2020 18:11:38
	System	19 Sep 2020 18:11:38

US3012329

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:53:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-09-19T13:11:26', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '9d3f12e2-44a3-4086-8a72-a3f283688b2b' User entered 'None (0)'	System	19 Sep 2020 18:11:38
	System	19 Sep 2020 18:11:38

US3012329

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:53:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-09-19T13:11:27', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '9d3f12e2-44a3-4086-8a72-a3f283688b2b' User entered 'None (0)'	System	19 Sep 2020 18:11:38
	System	19 Sep 2020 18:11:38

US3012329

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:53:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-09-19T13:11:29', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '9d3f12e2-44a3-4086-8a72-a3f283688b2b' User entered 'None (0)'	System	19 Sep 2020 18:11:38
	System	19 Sep 2020 18:11:38

US3012329

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:53:26

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)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-09-19T13:11:32', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '9d3f12e2-44a3-4086-8a72-a3f283688b2b' User entered 'No (N)'	System	19 Sep 2020 18:11:38
	System	19 Sep 2020 18:11:38

US3012329

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:53:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-09-19T13:11:36', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '9d3f12e2-44a3-4086-8a72-a3f283688b2b' User entered '19 Sep 2020 13:11'	System	19 Sep 2020 18:11:38
	System	19 Sep 2020 18:11:38

US3012329

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:53:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
User entered '19 Sep 2020 12:00'	System	15 Sep 2020 23:01:23

US3012329

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:53:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
User entered '20 Sep 2020 11:59'	System	15 Sep 2020 23:01:23

US3012329

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
Data entry locked.	System	15 Sep 2020 23:01:23
User entered 'Day 6'	System	15 Sep 2020 23:01:23

US3012329

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:53:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-09-20T12:01:13', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '261c3786-f0dc-4226-a90a-b90833cd2838' User entered 'None (0)'	System	20 Sep 2020 17:01:45
	System	20 Sep 2020 17:01:45

US3012329

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:53:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-09-20T12:01:17', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '261c3786-f0dc-4226-a90a-b90833cd2838' User entered 'None (0)'	System	20 Sep 2020 17:01:45
	System	20 Sep 2020 17:01:45

US3012329

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:53:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-09-20T12:01:20', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '261c3786-f0dc-4226-a90a-b90833cd2838' User entered 'None (0)'	System	20 Sep 2020 17:01:45
	System	20 Sep 2020 17:01:45

US3012329

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:53:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-09-20T12:01:21', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '261c3786-f0dc-4226-a90a-b90833cd2838' User entered 'None (0)'	System	20 Sep 2020 17:01:45
	System	20 Sep 2020 17:01:45

US3012329

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:53:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-09-20T12:01:22', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '261c3786-f0dc-4226-a90a-b90833cd2838' User entered 'None (0)'	System	20 Sep 2020 17:01:45
	System	20 Sep 2020 17:01:45

US3012329

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:53:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-09-20T12:01:24', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '261c3786-f0dc-4226-a90a-b90833cd2838' User entered 'None (0)'	System	20 Sep 2020 17:01:45
	System	20 Sep 2020 17:01:45

US3012329

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:53:26

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)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-09-20T12:01:27', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '261c3786-f0dc-4226-a90a-b90833cd2838' User entered 'No (N)'	System	20 Sep 2020 17:01:45
	System	20 Sep 2020 17:01:45

US3012329

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:53:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-09-20T12:01:30', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '261c3786-f0dc-4226-a90a-b90833cd2838' User entered '20 Sep 2020 12:01'	System	20 Sep 2020 17:01:45
	System	20 Sep 2020 17:01:45

US3012329

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:53:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
User entered '20 Sep 2020 12:00'	System	15 Sep 2020 23:01:23

US3012329

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:53:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
User entered '21 Sep 2020 11:59'	System	15 Sep 2020 23:01:23

US3012329

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
Data entry locked.	System	15 Sep 2020 23:01:23
User entered 'Day 7'	System	15 Sep 2020 23:01:23

US3012329

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:53:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-09-21T12:01:35', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '77bd6bf5-4876-4e5b-97e4-5408255e8b34' User entered 'None (0)'	System	21 Sep 2020 17:05:00
	System	21 Sep 2020 17:05:00

US3012329

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:53:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-09-21T12:01:37', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '77bd6bf5-4876-4e5b-97e4-5408255e8b34' User entered 'None (0)'	System	21 Sep 2020 17:05:00
	System	21 Sep 2020 17:05:00

US3012329

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:53:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-09-21T12:01:39', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '77bd6bf5-4876-4e5b-97e4-5408255e8b34' User entered 'None (0)'	System	21 Sep 2020 17:05:00
	System	21 Sep 2020 17:05:00

US3012329

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:53:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-09-21T12:01:41', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '77bd6bf5-4876-4e5b-97e4-5408255e8b34' User entered 'None (0)'	System	21 Sep 2020 17:05:00
	System	21 Sep 2020 17:05:00

US3012329

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:53:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-09-21T12:01:42', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '77bd6bf5-4876-4e5b-97e4-5408255e8b34' User entered 'None (0)'	System	21 Sep 2020 17:05:00
	System	21 Sep 2020 17:05:00

US3012329

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:53:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-09-21T12:01:44', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '77bd6bf5-4876-4e5b-97e4-5408255e8b34' User entered 'None (0)'	System	21 Sep 2020 17:05:00
	System	21 Sep 2020 17:05:00

US3012329

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:53:26

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)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-09-21T12:01:46', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '77bd6bf5-4876-4e5b-97e4-5408255e8b34' User entered 'No (N)'	System	21 Sep 2020 17:05:00
	System	21 Sep 2020 17:05:00

US3012329

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:53:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-09-21T12:01:50', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '77bd6bf5-4876-4e5b-97e4-5408255e8b34' User entered '21 Sep 2020 12:01'	System	21 Sep 2020 17:05:00
	System	21 Sep 2020 17:05:00

US3012329

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:53:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
User entered '21 Sep 2020 12:00'	System	15 Sep 2020 23:01:23

US3012329

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:53:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
User entered '22 Sep 2020 11:59'	System	15 Sep 2020 23:01:23

US3012329

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:53:26

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered 'Yes (Y)'	Tambra Dora (b) (4)	23 Sep 2020 22:00:10

US3012329

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:53:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered '23 Sep 2020'	Tambra Dora (b) (4)	23 Sep 2020 22:00:10

US3012329

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:53:26

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered 'Contact Made (CONTACT MADE)'	Tambra Dora (b) (4)	23 Sep 2020 22:00:10

US3012329

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:53:26

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered empty.	(b) (4) Tambra Dora (b) (4) (b) (4)	23 Sep 2020 22:00:10

US3012329

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:53:26

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered 'Yes (Y)'	Tambra Dora (b) (4)	23 Sep 2020 22:00:14

US3012329

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:53:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User entered 'I'	System	23 Sep 2020 22:00:14

US3012329

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:53:26

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered 'Yes (Y)'	Katherine Davis (b) (4)	30 Sep 2020 00:45:35

US3012329

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:53:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered '29 Sep 2020'	Katherine Davis (b) (4)	30 Sep 2020 00:45:35

US3012329

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:53:26

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered 'Contact Made (CONTACT MADE)'	Katherine Davis (b) (4)	30 Sep 2020 00:45:35

US3012329

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:53:26

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered empty.	(b) (4) Katherine Davis (b) (4)	30 Sep 2020 00:45:35

US3012329

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:53:26

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered 'Yes (Y)'	Katherine Davis (b) (4)	30 Sep 2020 00:45:40

US3012329

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:53:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User entered '1'	System	30 Sep 2020 00:45:40

US3012329

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:53:26

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered 'Yes (Y)'	Tambra Dora (b) (4)	06 Oct 2020 20:12:43

US3012329

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:53:26

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered '6 Oct 2020'	Tambra Dora (b) (4)	06 Oct 2020 20:12:43

US3012329

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:53:26

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered 'Contact Made (CONTACT MADE)'	Tambra Dora (b) (4)	06 Oct 2020 20:12:43

US3012329

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:53:26

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered empty.	(b) (4) Tambra Dora (b) (4) (b) (4)	06 Oct 2020 20:12:43

US3012329

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:53:26

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered 'Yes (Y)'	Tambra Dora (b) (4)	06 Oct 2020 20:12:47

US3012329

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:53:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User entered 'I'	System	06 Oct 2020 20:12:47

US3012329

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:53:26

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered 'Yes (Y)'	(b) (4) Katherine Davis (b) (4)	13 Oct 2020 22:19:22

US3012329

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:53:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered '13 Oct 2020'	(b) (4) Katherine Davis (b) (4)	13 Oct 2020 22:19:22

US3012329

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:53:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered 'Clinic (Clinic)'	Katherine Davis (b) (4)	13 Oct 2020 22:19:22

US3012329

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:53:26

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User entered 'VISIT2'	System	13 Oct 2020 22:19:22

US3012329

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:53:26

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User accepted default value 'Pre-Dose (PREDOSE)'	Katherine Davis (b) (4)	13 Oct 2020 22:20:13
	(b) (4)	

US3012329

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:53:26

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered 'Yes (Y)'	Katherine Davis (b) (4)	13 Oct 2020 22:20:13

US3012329

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:53:26

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered '13 Oct 2020'	Katherine Davis (b) (4)	13 Oct 2020 22:20:13

US3012329

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:53:26

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered '16:14'	Katherine Davis (b) (4)	13 Oct 2020 22:20:13

US3012329

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:53:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User entered '13 Oct 2020 16:14'	System	13 Oct 2020 22:20:13

US3012329

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:53:26

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered '98.1' F	Katherine Davis (b) (4)	13 Oct 2020 22:20:13

US3012329

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:53:26

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered 'Oral (Oral)'	(b) (4) Katherine Davis (b) (4)	13 Oct 2020 22:20:13

US3012329

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:53:26

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered empty.	(b) (4) Katherine Davis (b) (4)	13 Oct 2020 22:20:13

US3012329

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:53:26

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered '79'	(b) (4) Katherine Davis (b) (4)	13 Oct 2020 22:20:13

US3012329

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:53:26

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User entered 'bpm'	System	13 Oct 2020 22:20:13

US3012329

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:53:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered '14'	Katherine Davis (b) (4)	13 Oct 2020 22:20:13

US3012329

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:53:26

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User entered 'breaths/min'	System	13 Oct 2020 22:20:13

US3012329

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:53:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered '125'	(b) (4) Katherine Davis (b) (4)	13 Oct 2020 22:20:13

US3012329

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:53:26

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User entered 'mmHg'	System	13 Oct 2020 22:20:13

US3012329

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:53:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered '79'	(b) (4) Katherine Davis (b) (4) (b) (4)	13 Oct 2020 22:20:13

US3012329

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:53:26

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User entered 'mmHg'	System	13 Oct 2020 22:20:13

US3012329

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:53:26

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User accepted default value 'Post-Dose (POSTDOSE)'	Katherine Davis (b) (4)	13 Oct 2020 23:09:06

US3012329

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:53:26

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered 'Yes (Y)'	Katherine Davis (b) (4)	13 Oct 2020 23:09:06

US3012329

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:53:26

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered '13 Oct 2020'	Katherine Davis (b) (4)	13 Oct 2020 23:09:06

US3012329

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:53:26

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered '18:07'	Katherine Davis (b) (4)	13 Oct 2020 23:09:06

US3012329

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:53:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User entered '13 Oct 2020 18:07'	System	13 Oct 2020 23:09:06

US3012329

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:53:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered '98.4' F	Katherine Davis (b) (4)	13 Oct 2020 23:09:06

US3012329

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:53:26

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered 'Oral (Oral)'	Katherine Davis (b) (4)	13 Oct 2020 23:09:06

US3012329

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:53:26

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered empty.	Katherine Davis (b) (4)	13 Oct 2020 23:09:06

US3012329

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:53:26

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered '68'	Katherine Davis (b) (4)	13 Oct 2020 23:09:06

US3012329

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:53:26

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User entered 'bpm'	System	13 Oct 2020 23:09:06

US3012329

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:53:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered '16'	Katherine Davis (b) (4)	13 Oct 2020 23:09:06

US3012329

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:53:26

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User entered 'breaths/min'	System	13 Oct 2020 23:09:06

US3012329

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:53:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered '130'	(b) (4) Katherine Davis (b) (4)	13 Oct 2020 23:09:06

US3012329

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:53:26

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User entered 'mmHg'	System	13 Oct 2020 23:09:06

US3012329

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:53:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered '84'	(b) (4) Katherine Davis (b) (4)	13 Oct 2020 23:09:06

US3012329

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:53:26

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User entered 'mmHg'	System	13 Oct 2020 23:09:06

US3012329

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:53:26

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered 'Yes (Y)'	Katherine Davis (b) (4)	13 Oct 2020 22:20:25

US3012329

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:53:26

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered '13 Oct 2020'	(b) (4) Katherine Davis (b) (4) (b) (4)	13 Oct 2020 22:20:25

US3012329

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:53:26

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered 'Yes (Y)'	(b) (4) Katherine Davis (b) (4)	13 Oct 2020 22:36:32

US3012329

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:53:26

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered empty.	(b) (4) Katherine Davis (b) (4)	13 Oct 2020 22:36:32

US3012329

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:53:26

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)	27 Mar 2021 17:32:06
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered empty.	Katherine Davis (b) (4)	13 Oct 2020 22:36:32

US3012329

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:53:26

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User entered 'MRNA-1273 OR PLACEBO'	System	13 Oct 2020 22:36:32

US3012329

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:53:26

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered '13 Oct 2020'	Katherine Davis (b) (4)	13 Oct 2020 22:36:32

US3012329

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:53:26

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered '17:29'	Katherine Davis (b) (4)	13 Oct 2020 22:36:32

US3012329

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:53:26

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User entered '13 Oct 2020 17:29'	System	13 Oct 2020 22:36:32

US3012329

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:53:26

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered 'Left Arm (LEFT ARM)'	Katherine Davis (b) (4)	13 Oct 2020 22:36:32

US3012329

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:53:26

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User entered 'ONCE'	System	13 Oct 2020 22:36:32

US3012329

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:53:26

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User entered 'INTRAMUSCULAR'	System	13 Oct 2020 22:36:32

US3012329

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:53:26

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered 'Yes (Y)'	Katherine Davis (b) (4)	13 Oct 2020 22:21:19

US3012329

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:53:26

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered '13 Oct 2020'	(b) (4) Katherine Davis (b) (4)	13 Oct 2020 22:21:19

US3012329

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:53:26

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered '16:53'	Katherine Davis (b) (4)	13 Oct 2020 22:21:19

US3012329

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:53:26

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User entered '13 Oct 2020 16:53'	System	13 Oct 2020 22:21:19

US3012329

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 21:53:26

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered '13 Oct 2020'	Katherine Davis (b) (4)	13 Oct 2020 22:21:48

US3012329

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 21:53:26

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Katherine Davis (b) (4)	13 Oct 2020 22:21:48

US3012329

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 21:53:26

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered 'Yes (Y)'	(b) (4) Katherine Davis (b) (4)	13 Oct 2020 22:21:48

US3012329

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 21:53:26

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered '16:45'	Katherine Davis (b) (4)	13 Oct 2020 22:21:48

US3012329

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 21:53:26

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User entered '13 Oct 2020 16:45'	System	13 Oct 2020 22:21:48

US3012329

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 21:53:26

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Katherine Davis (b) (4)	13 Oct 2020 22:21:48

US3012329

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 21:53:26

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered 'No (N)'	(b) (4) Katherine Davis (b) (4)	13 Oct 2020 22:21:48

US3012329

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 21:53:26

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered empty.	Katherine Davis (b) (4)	13 Oct 2020 22:21:48

US3012329

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 21:53:26

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User entered empty.	System	13 Oct 2020 22:21:48

US3012329

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:53:26

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered 'Yes (Y)'	Katherine Davis (b) (4)	13 Oct 2020 22:22:02

US3012329

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:53:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User entered '1'	System	13 Oct 2020 22:22:02

US3012329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
Data entry locked.	System	13 Oct 2020 22:36:32
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	13 Oct 2020 22:36:32

US3012329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 21:53:26

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-10-13T18:03:05', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: 'e8d42124-de23-41b0-b5fa-aa13d084205a' User entered 'Yes (Y)'	System	13 Oct 2020 23:03:22
	System	13 Oct 2020 23:03:22

US3012329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 21:53:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-10-13T18:03:10', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: 'e8d42124-de23-41b0-b5fa-aa13d084205a' User entered '98.4'	System	13 Oct 2020 23:03:22
	System	13 Oct 2020 23:03:22

US3012329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 21:53:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-10-13T18:03:15', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: 'e8d42124-de23-41b0-b5fa-aa13d084205a' User entered 'No (N)'	System	13 Oct 2020 23:03:22
	System	13 Oct 2020 23:03:22

US3012329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 21:53:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-10-13T18:03:18', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: 'e8d42124-de23-41b0-b5fa-aa13d084205a' User entered '13 Oct 2020 18:03'	System	13 Oct 2020 23:03:22
	System	13 Oct 2020 23:03:22

US3012329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 21:53:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
User entered '13 Oct 2020 17:49'	System	13 Oct 2020 22:36:32

US3012329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 21:53:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
User entered '13 Oct 2020 20:19'	System	13 Oct 2020 22:36:32

US3012329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
Data entry locked.	System	13 Oct 2020 22:36:32
User entered 'Day 1, after vaccination (at home)'	System	13 Oct 2020 22:36:32

US3012329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 21:53:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-10-13T23:34:04', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: 'd0f216d1-cf1d-4407-a566-3a9e965404ed' User entered 'Yes (Y)'	System	14 Oct 2020 04:34:21
	System	14 Oct 2020 04:34:21

US3012329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 21:53:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-10-13T23:34:10', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: 'd0f216d1-cf1d-4407-a566-3a9e965404ed' User entered '97.6'	System	14 Oct 2020 04:34:21
	System	14 Oct 2020 04:34:21

US3012329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 21:53:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-10-13T23:34:15', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: 'd0f216d1-cf1d-4407-a566-3a9e965404ed' User entered 'No (N)'	System	14 Oct 2020 04:34:21
	System	14 Oct 2020 04:34:21

US3012329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 21:53:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-10-13T23:34:18', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: 'd0f216d1-cf1d-4407-a566-3a9e965404ed' User entered '13 Oct 2020 23:34'	System	14 Oct 2020 04:34:21
	System	14 Oct 2020 04:34:21

US3012329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 21:53:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
User entered '13 Oct 2020 21:14'	System	13 Oct 2020 22:36:32

US3012329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 21:53:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
User entered '14 Oct 2020 11:59'	System	13 Oct 2020 22:36:32

US3012329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
Data entry locked.	System	13 Oct 2020 22:36:32
User entered 'Day 2'	System	13 Oct 2020 22:36:32

US3012329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 21:53:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-10-14T14:29:29', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: 'f9ae24a6-422c-4727-ae82-f2c763d4de2e' User entered 'Yes (Y)'	System	14 Oct 2020 19:29:46
	System	14 Oct 2020 19:29:46

US3012329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 21:53:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-10-14T14:29:34', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: 'f9ae24a6-422c-4727-ae82-f2c763d4de2e' User entered '97.6'	System	14 Oct 2020 19:29:46
	System	14 Oct 2020 19:29:46

US3012329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 21:53:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-10-14T14:29:38', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: 'f9ae24a6-422c-4727-ae82-f2c763d4de2e' User entered 'No (N)'	System	14 Oct 2020 19:29:46
	System	14 Oct 2020 19:29:46

US3012329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 21:53:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-10-14T14:29:41', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: 'f9ae24a6-422c-4727-ae82-f2c763d4de2e' User entered '14 Oct 2020 14:29'	System	14 Oct 2020 19:29:46
	System	14 Oct 2020 19:29:46

US3012329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 21:53:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
User entered '14 Oct 2020 12:00'	System	13 Oct 2020 22:36:32

US3012329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 21:53:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
User entered '15 Oct 2020 11:59'	System	13 Oct 2020 22:36:32

US3012329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
Data entry locked.	System	13 Oct 2020 22:36:32
User entered 'Day 3'	System	13 Oct 2020 22:36:32

US3012329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 21:53:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-10-15T12:16:30', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: 'aa76277a-5e9f-4def-8340-65e9f6678392'	System	15 Oct 2020 17:16:46
User entered 'Yes (Y)'	System	15 Oct 2020 17:16:46

US3012329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 21:53:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-10-15T12:16:37', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: 'aa76277a-5e9f-4def-8340-65e9f6678392' User entered '97.5'	System	15 Oct 2020 17:16:46
	System	15 Oct 2020 17:16:46

US3012329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 21:53:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-10-15T12:16:40', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: 'aa76277a-5e9f-4def-8340-65e9f6678392'	System	15 Oct 2020 17:16:46
User entered 'No (N)'	System	15 Oct 2020 17:16:46

US3012329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 21:53:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-10-15T12:16:43', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: 'aa76277a-5e9f-4def-8340-65e9f6678392'	System	15 Oct 2020 17:16:46
User entered '15 Oct 2020 12:16'	System	15 Oct 2020 17:16:46

US3012329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 21:53:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
User entered '15 Oct 2020 12:00'	System	13 Oct 2020 22:36:32

US3012329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 21:53:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
User entered '16 Oct 2020 11:59'	System	13 Oct 2020 22:36:32

US3012329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
Data entry locked.	System	13 Oct 2020 22:36:32
User entered 'Day 4'	System	13 Oct 2020 22:36:32

US3012329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 21:53:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-10-16T14:10:35', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '5e09c329-0104-4817-8d51-f950578a5b5d' User entered 'Yes (Y)'	System	16 Oct 2020 19:10:49
	System	16 Oct 2020 19:10:49

US3012329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 21:53:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-10-16T14:10:41', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '5e09c329-0104-4817-8d51-f950578a5b5d' User entered '97.5'	System	16 Oct 2020 19:10:49
	System	16 Oct 2020 19:10:49

US3012329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 21:53:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-10-16T14:10:43', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '5e09c329-0104-4817-8d51-f950578a5b5d' User entered 'No (N)'	System	16 Oct 2020 19:10:49
	System	16 Oct 2020 19:10:49

US3012329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 21:53:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-10-16T14:10:47', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '5e09c329-0104-4817-8d51-f950578a5b5d' User entered '16 Oct 2020 14:10'	System	16 Oct 2020 19:10:49
	System	16 Oct 2020 19:10:49

US3012329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 21:53:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
User entered '16 Oct 2020 12:00'	System	13 Oct 2020 22:36:32

US3012329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 21:53:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
User entered '17 Oct 2020 11:59'	System	13 Oct 2020 22:36:32

US3012329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
Data entry locked.	System	13 Oct 2020 22:36:32
User entered 'Day 5'	System	13 Oct 2020 22:36:32

US3012329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 21:53:26

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-10-17T19:52:47', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: 'fbd7a246-1437-4e5d-986d-dbfcd1756014' User entered 'Yes (Y)'	System	18 Oct 2020 00:53:00
	System	18 Oct 2020 00:53:00

US3012329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 21:53:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-10-17T19:52:52', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: 'fbd7a246-1437-4e5d-986d-dbf1756014' User entered '97.5'	System	18 Oct 2020 00:53:00
	System	18 Oct 2020 00:53:00

US3012329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 21:53:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-10-17T19:52:55', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: 'fbd7a246-1437-4e5d-986d-dbf1756014' User entered 'No (N)'	System	18 Oct 2020 00:53:00
	System	18 Oct 2020 00:53:00

US3012329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 21:53:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-10-17T19:52:57', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: 'fbd7a246-1437-4e5d-986d-dbf1756014' User entered '17 Oct 2020 19:52'	System	18 Oct 2020 00:53:00
	System	18 Oct 2020 00:53:00

US3012329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 21:53:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
User entered '17 Oct 2020 12:00'	System	13 Oct 2020 22:36:32

US3012329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 21:53:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
User entered '18 Oct 2020 11:59'	System	13 Oct 2020 22:36:32

US3012329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
Data entry locked.	System	13 Oct 2020 22:36:32
User entered 'Day 6'	System	13 Oct 2020 22:36:32

US3012329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 21:53:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-10-18T20:27:52', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: 'a0785534-d5a3-4903-8cbc-90e558d755a1' User entered 'Yes (Y)'	System	19 Oct 2020 01:28:05
	System	19 Oct 2020 01:28:05

US3012329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 21:53:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-10-18T20:27:57', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: 'a0785534-d5a3-4903-8cbc-90e558d755a1' User entered '97.6'	System	19 Oct 2020 01:28:05
	System	19 Oct 2020 01:28:05

US3012329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 21:53:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-10-18T20:28:00', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: 'a0785534-d5a3-4903-8cbc-90e558d755a1' User entered 'No (N)'	System	19 Oct 2020 01:28:05
	System	19 Oct 2020 01:28:05

US3012329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 21:53:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-10-18T20:28:04', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: 'a0785534-d5a3-4903-8cbc-90e558d755a1' User entered '18 Oct 2020 20:28'	System	19 Oct 2020 01:28:05
	System	19 Oct 2020 01:28:05

US3012329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 21:53:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
User entered '18 Oct 2020 12:00'	System	13 Oct 2020 22:36:32

US3012329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 21:53:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
User entered '19 Oct 2020 11:59'	System	13 Oct 2020 22:36:32

US3012329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
Data entry locked.	System	13 Oct 2020 22:36:32
User entered 'Day 7'	System	13 Oct 2020 22:36:32

US3012329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 21:53:26

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-10-19T12:00:36', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: 'f86c1cf2-a082-41b1-9837-d350d987aa7b' User entered 'Yes (Y)'	System	19 Oct 2020 17:01:26
	System	19 Oct 2020 17:01:26

US3012329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 21:53:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-10-19T12:01:15', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: 'f86c1cf2-a082-41b1-9837-d350d987aa7b' User entered '97.5'	System	19 Oct 2020 17:01:26
	System	19 Oct 2020 17:01:26

US3012329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 21:53:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-10-19T12:01:19', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: 'f86c1cf2-a082-41b1-9837-d350d987aa7b' User entered 'No (N)'	System	19 Oct 2020 17:01:26
	System	19 Oct 2020 17:01:26

US3012329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 21:53:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-10-19T12:01:23', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: 'f86c1cf2-a082-41b1-9837-d350d987aa7b' User entered '19 Oct 2020 12:01'	System	19 Oct 2020 17:01:26
	System	19 Oct 2020 17:01:26

US3012329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 21:53:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
User entered '19 Oct 2020 12:00'	System	13 Oct 2020 22:36:32

US3012329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 21:53:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
User entered '20 Oct 2020 11:59'	System	13 Oct 2020 22:36:32

US3012329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
Data entry locked.	System	13 Oct 2020 22:36:32
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	13 Oct 2020 22:36:32

US3012329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 21:53:26

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-10-13T18:03:33', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: 'e5011a67-6ed1-4e37-ae93-28a5f0ae9e0b' User entered 'None (1)'	System	13 Oct 2020 23:03:47
	System	13 Oct 2020 23:03:47

US3012329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 21:53:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-10-13T18:03:36', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: 'e5011a67-6ed1-4e37-ae93-28a5f0ae9e0b' User entered 'No (N)'	System	13 Oct 2020 23:03:47
	System	13 Oct 2020 23:03:47

US3012329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 21:53:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-10-13T18:03:39', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: 'e5011a67-6ed1-4e37-ae93-28a5f0ae9e0b' User entered 'No (N)'	System	13 Oct 2020 23:03:47
	System	13 Oct 2020 23:03:47

US3012329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 21:53:26

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-10-13T18:03:40', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: 'e5011a67-6ed1-4e37-ae93-28a5f0ae9e0b' User entered 'None (1)'	System	13 Oct 2020 23:03:47
	System	13 Oct 2020 23:03:47

US3012329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 21:53:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-10-13T18:03:43', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: 'e5011a67-6ed1-4e37-ae93-28a5f0ae9e0b' User entered '13 Oct 2020 18:03'	System	13 Oct 2020 23:03:47
	System	13 Oct 2020 23:03:47

US3012329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 21:53:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
User entered '13 Oct 2020 17:49'	System	13 Oct 2020 22:36:32

US3012329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 21:53:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
User entered '13 Oct 2020 20:19'	System	13 Oct 2020 22:36:32

US3012329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
Data entry locked.	System	13 Oct 2020 22:36:32
User entered 'Day 1, after vaccination (at home)'	System	13 Oct 2020 22:36:32

US3012329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 21:53:26

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-10-13T23:34:23', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '8b956eb4-f7b0-49a0-a3ed-b45a60eadeca' User entered 'None (1)'	System	14 Oct 2020 04:34:37
	System	14 Oct 2020 04:34:37

US3012329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 21:53:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-10-13T23:34:25', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '8b956eb4-f7b0-49a0-a3ed-b45a60eadeca' User entered 'No (N)'	System	14 Oct 2020 04:34:37
	System	14 Oct 2020 04:34:37

US3012329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 21:53:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-10-13T23:34:29', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '8b956eb4-f7b0-49a0-a3ed-b45a60eadeca' User entered 'No (N)'	System	14 Oct 2020 04:34:37
	System	14 Oct 2020 04:34:37

US3012329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 21:53:26

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-10-13T23:34:31', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '8b956eb4-f7b0-49a0-a3ed-b45a60eadeca' User entered 'None (1)'	System	14 Oct 2020 04:34:37
	System	14 Oct 2020 04:34:37

US3012329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 21:53:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-10-13T23:34:34', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '8b956eb4-f7b0-49a0-a3ed-b45a60eadeca' User entered '13 Oct 2020 23:34'	System	14 Oct 2020 04:34:37
	System	14 Oct 2020 04:34:37

US3012329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 21:53:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
User entered '13 Oct 2020 21:14'	System	13 Oct 2020 22:36:32

US3012329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 21:53:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
User entered '14 Oct 2020 11:59'	System	13 Oct 2020 22:36:32

US3012329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
Data entry locked.	System	13 Oct 2020 22:36:32
User entered 'Day 2'	System	13 Oct 2020 22:36:32

US3012329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 21:53:26

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-10-14T14:29:45', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '2dc0c0f2-822a-463f-a210-0ee84f8ade40'	System	14 Oct 2020 19:29:57
User entered 'None (1)'	System	14 Oct 2020 19:29:57

US3012329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 21:53:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-10-14T14:29:47', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '2dc0c0f2-822a-463f-a210-0ee84f8ade40' User entered 'No (N)'	System	14 Oct 2020 19:29:57
	System	14 Oct 2020 19:29:57

US3012329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 21:53:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-10-14T14:29:48', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '2dc0c0f2-822a-463f-a210-0ee84f8ade40' User entered 'No (N)'	System	14 Oct 2020 19:29:57
	System	14 Oct 2020 19:29:57

US3012329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 21:53:26

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-10-14T14:29:50', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '2dc0c0f2-822a-463f-a210-0ee84f8ade40'	System	14 Oct 2020 19:29:57
User entered 'None (1)'	System	14 Oct 2020 19:29:57

US3012329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 21:53:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-10-14T14:29:52', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '2dc0c0f2-822a-463f-a210-0ee84f8ade40' User entered '14 Oct 2020 14:29'	System	14 Oct 2020 19:29:57
	System	14 Oct 2020 19:29:57

US3012329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 21:53:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
User entered '14 Oct 2020 12:00'	System	13 Oct 2020 22:36:32

US3012329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 21:53:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
User entered '15 Oct 2020 11:59'	System	13 Oct 2020 22:36:32

US3012329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
Data entry locked.	System	13 Oct 2020 22:36:32
User entered 'Day 3'	System	13 Oct 2020 22:36:32

US3012329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 21:53:26

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-10-15T12:16:47', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: 'b6ce2010-40db-4778-adc5-4afd65fbea5e' User entered 'None (1)'	System	15 Oct 2020 17:17:01
	System	15 Oct 2020 17:17:01

US3012329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 21:53:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-10-15T12:16:50', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: 'b6ce2010-40db-4778-adc5-4afd65fbea5e' User entered 'No (N)'	System	15 Oct 2020 17:17:01
	System	15 Oct 2020 17:17:01

US3012329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 21:53:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-10-15T12:16:52', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: 'b6ce2010-40db-4778-adc5-4afd65fbea5e' User entered 'No (N)'	System	15 Oct 2020 17:17:01
	System	15 Oct 2020 17:17:01

US3012329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 21:53:26

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-10-15T12:16:54', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: 'b6ce2010-40db-4778-adc5-4afd65fbea5e' User entered 'None (1)'	System	15 Oct 2020 17:17:01
	System	15 Oct 2020 17:17:01

US3012329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 21:53:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-10-15T12:16:58', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: 'b6ce2010-40db-4778-adc5-4afd65fbea5e' User entered '15 Oct 2020 12:16'	System	15 Oct 2020 17:17:01
	System	15 Oct 2020 17:17:01

US3012329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 21:53:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
User entered '15 Oct 2020 12:00'	System	13 Oct 2020 22:36:32

US3012329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 21:53:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
User entered '16 Oct 2020 11:59'	System	13 Oct 2020 22:36:32

US3012329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
Data entry locked.	System	13 Oct 2020 22:36:32
User entered 'Day 4'	System	13 Oct 2020 22:36:32

US3012329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 21:53:26

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-10-16T14:10:50', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '41afbcb-662b-4d02-a5f4-76ef2f2487b7' User entered 'None (1)'	System	16 Oct 2020 19:11:01
	System	16 Oct 2020 19:11:01

US3012329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 21:53:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-10-16T14:10:52', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '41afbbcb-662b-4d02-a5f4-76ef2f2487b7' User entered 'No (N)'	System	16 Oct 2020 19:11:01
	System	16 Oct 2020 19:11:01

US3012329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 21:53:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-10-16T14:10:54', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '41afbbcb-662b-4d02-a5f4-76ef2f2487b7' User entered 'No (N)'	System	16 Oct 2020 19:11:01
	System	16 Oct 2020 19:11:01

US3012329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 21:53:26

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-10-16T14:10:55', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '41afbbcb-662b-4d02-a5f4-76ef2f2487b7' User entered 'None (1)'	System	16 Oct 2020 19:11:01
	System	16 Oct 2020 19:11:01

US3012329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 21:53:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-10-16T14:10:58', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '41afbbcb-662b-4d02-a5f4-76ef2f2487b7' User entered '16 Oct 2020 14:10'	System	16 Oct 2020 19:11:01
	System	16 Oct 2020 19:11:01

US3012329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 21:53:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
User entered '16 Oct 2020 12:00'	System	13 Oct 2020 22:36:32

US3012329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 21:53:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
User entered '17 Oct 2020 11:59'	System	13 Oct 2020 22:36:32

US3012329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
Data entry locked.	System	13 Oct 2020 22:36:32
User entered 'Day 5'	System	13 Oct 2020 22:36:32

US3012329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 21:53:26

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-10-17T19:53:06', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '7a8c9fd8-3243-4fdd-8236-ce0c71b937f2'	System	18 Oct 2020 00:53:19
User entered 'None (1)'	System	18 Oct 2020 00:53:19

US3012329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 21:53:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-10-17T19:53:12', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '7a8c9fd8-3243-4fdd-8236-ce0c71b937f2'	System	18 Oct 2020 00:53:19
User entered 'No (N)'	System	18 Oct 2020 00:53:19

US3012329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 21:53:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-10-17T19:53:14', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '7a8c9fd8-3243-4fdd-8236-ce0c71b937f2'	System	18 Oct 2020 00:53:19
User entered 'No (N)'	System	18 Oct 2020 00:53:19

US3012329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 21:53:26

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-10-17T19:53:16', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '7a8c9fd8-3243-4fdd-8236-ce0c71b937f2'	System	18 Oct 2020 00:53:19
User entered 'None (1)'	System	18 Oct 2020 00:53:19

US3012329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 21:53:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-10-17T19:53:18', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '7a8c9fd8-3243-4fdd-8236-ce0c71b937f2' User entered '17 Oct 2020 19:53'	System	18 Oct 2020 00:53:19
	System	18 Oct 2020 00:53:19

US3012329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 21:53:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
User entered '17 Oct 2020 12:00'	System	13 Oct 2020 22:36:32

US3012329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 21:53:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
User entered '18 Oct 2020 11:59'	System	13 Oct 2020 22:36:32

US3012329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
Data entry locked.	System	13 Oct 2020 22:36:32
User entered 'Day 6'	System	13 Oct 2020 22:36:32

US3012329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 21:53:26

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-10-18T20:28:07', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '375ddce1-9e8f-44a9-8212-1c664fcd42e5' User entered 'None (1)'	System	19 Oct 2020 01:28:18
	System	19 Oct 2020 01:28:18

US3012329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 21:53:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-10-18T20:28:10', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '375ddce1-9e8f-44a9-8212-1c664fcd42e5' User entered 'No (N)'	System	19 Oct 2020 01:28:18
	System	19 Oct 2020 01:28:18

US3012329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 21:53:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-10-18T20:28:12', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '375ddce1-9e8f-44a9-8212-1c664fcd42e5' User entered 'No (N)'	System	19 Oct 2020 01:28:18
	System	19 Oct 2020 01:28:18

US3012329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 21:53:26

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-10-18T20:28:13', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '375ddce1-9e8f-44a9-8212-1c664fcd42e5'	System	19 Oct 2020 01:28:18
User entered 'None (1)'	System	19 Oct 2020 01:28:18

US3012329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 21:53:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-10-18T20:28:16', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '375ddce1-9e8f-44a9-8212-1c664fcd42e5' User entered '18 Oct 2020 20:28'	System	19 Oct 2020 01:28:18
	System	19 Oct 2020 01:28:18

US3012329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 21:53:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
User entered '18 Oct 2020 12:00'	System	13 Oct 2020 22:36:32

US3012329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 21:53:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
User entered '19 Oct 2020 11:59'	System	13 Oct 2020 22:36:32

US3012329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
Data entry locked.	System	13 Oct 2020 22:36:32
User entered 'Day 7'	System	13 Oct 2020 22:36:32

US3012329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 21:53:26

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-10-19T12:01:28', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '8a68ec62-8159-40ff-85bf-7aee6dc37ef2'	System	19 Oct 2020 17:02:09
User entered 'None (1)'	System	19 Oct 2020 17:02:09

US3012329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 21:53:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-10-19T12:01:30', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '8a68ec62-8159-40ff-85bf-7aee6dc37ef2' User entered 'No (N)'	System	19 Oct 2020 17:02:09
	System	19 Oct 2020 17:02:09

US3012329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 21:53:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-10-19T12:01:33', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '8a68ec62-8159-40ff-85bf-7aee6dc37ef2' User entered 'No (N)'	System	19 Oct 2020 17:02:09
	System	19 Oct 2020 17:02:09

US3012329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 21:53:26

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-10-19T12:01:56', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '8a68ec62-8159-40ff-85bf-7aee6dc37ef2'	System	19 Oct 2020 17:02:09
User entered 'None (1)'	System	19 Oct 2020 17:02:09

US3012329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 21:53:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-10-19T12:02:05', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '8a68ec62-8159-40ff-85bf-7aee6dc37ef2' User entered '19 Oct 2020 12:02'	System	19 Oct 2020 17:02:09
	System	19 Oct 2020 17:02:09

US3012329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 21:53:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
User entered '19 Oct 2020 12:00'	System	13 Oct 2020 22:36:32

US3012329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 21:53:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
User entered '20 Oct 2020 11:59'	System	13 Oct 2020 22:36:32

US3012329

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
Data entry locked.	System	13 Oct 2020 22:36:32
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	13 Oct 2020 22:36:32

US3012329

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:53:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-10-13T18:03:48', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '9524f30a-c480-46f0-89c1-ab4c71a84301' User entered 'None (0)'	System	13 Oct 2020 23:04:10
	System	13 Oct 2020 23:04:10

US3012329

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:53:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-10-13T18:03:49', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '9524f30a-c480-46f0-89c1-ab4c71a84301' User entered 'None (0)'	System	13 Oct 2020 23:04:10
	System	13 Oct 2020 23:04:10

US3012329

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:53:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-10-13T18:03:52', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '9524f30a-c480-46f0-89c1-ab4c71a84301' User entered 'None (0)'	System	13 Oct 2020 23:04:10
	System	13 Oct 2020 23:04:10

US3012329

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:53:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-10-13T18:03:53', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '9524f30a-c480-46f0-89c1-ab4c71a84301' User entered 'None (0)'	System	13 Oct 2020 23:04:10
	System	13 Oct 2020 23:04:10

US3012329

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:53:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-10-13T18:03:56', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '9524f30a-c480-46f0-89c1-ab4c71a84301' User entered 'None (0)'	System	13 Oct 2020 23:04:10
	System	13 Oct 2020 23:04:10

US3012329

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:53:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-10-13T18:03:58', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '9524f30a-c480-46f0-89c1-ab4c71a84301' User entered 'None (0)'	System	13 Oct 2020 23:04:10
	System	13 Oct 2020 23:04:10

US3012329

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:53:26

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)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-10-13T18:04:00', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '9524f30a-c480-46f0-89c1-ab4c71a84301' User entered 'No (N)'	System	13 Oct 2020 23:04:10
	System	13 Oct 2020 23:04:10

US3012329

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:53:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-10-13T18:04:03', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '9524f30a-c480-46f0-89c1-ab4c71a84301' User entered '13 Oct 2020 18:04'	System	13 Oct 2020 23:04:10
	System	13 Oct 2020 23:04:10

US3012329

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:53:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
User entered '13 Oct 2020 17:49'	System	13 Oct 2020 22:36:32

US3012329

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:53:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
User entered '13 Oct 2020 20:19'	System	13 Oct 2020 22:36:32

US3012329

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
Data entry locked.	System	13 Oct 2020 22:36:32
User entered 'Day 1, after vaccination (at home)'	System	13 Oct 2020 22:36:32

US3012329

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:53:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-10-13T23:34:37', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: 'dd82d4c6-685a-40b3-9747-d13876e11aac' User entered 'None (0)'	System	14 Oct 2020 04:34:57
	System	14 Oct 2020 04:34:57

US3012329

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:53:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-10-13T23:34:40', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: 'dd82d4c6-685a-40b3-9747-d13876e11aac' User entered 'None (0)'	System	14 Oct 2020 04:34:57
	System	14 Oct 2020 04:34:57

US3012329

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:53:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-10-13T23:34:42', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: 'dd82d4c6-685a-40b3-9747-d13876e11aac' User entered 'None (0)'	System	14 Oct 2020 04:34:57
	System	14 Oct 2020 04:34:57

US3012329

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:53:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-10-13T23:34:44', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: 'dd82d4c6-685a-40b3-9747-d13876e11aac' User entered 'None (0)'	System	14 Oct 2020 04:34:57
	System	14 Oct 2020 04:34:57

US3012329

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:53:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-10-13T23:34:46', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: 'dd82d4c6-685a-40b3-9747-d13876e11aac' User entered 'None (0)'	System	14 Oct 2020 04:34:57
	System	14 Oct 2020 04:34:57

US3012329

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:53:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-10-13T23:34:48', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: 'dd82d4c6-685a-40b3-9747-d13876e11aac' User entered 'None (0)'	System	14 Oct 2020 04:34:57
	System	14 Oct 2020 04:34:57

US3012329

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:53:26

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)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-10-13T23:34:51', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: 'dd82d4c6-685a-40b3-9747-d13876e11aac' User entered 'No (N)'	System	14 Oct 2020 04:34:57
	System	14 Oct 2020 04:34:57

US3012329

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:53:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-10-13T23:34:53', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: 'dd82d4c6-685a-40b3-9747-d13876e11aac' User entered '13 Oct 2020 23:34'	System	14 Oct 2020 04:34:57
	System	14 Oct 2020 04:34:57

US3012329

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:53:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
User entered '13 Oct 2020 21:14'	System	13 Oct 2020 22:36:32

US3012329

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:53:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
User entered '14 Oct 2020 11:59'	System	13 Oct 2020 22:36:32

US3012329

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
Data entry locked.	System	13 Oct 2020 22:36:32
User entered 'Day 2'	System	13 Oct 2020 22:36:32

US3012329

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:53:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-10-14T14:29:55', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '9b9de7f5-8a3e-4930-9749-b16cf7240aa1' User entered 'None (0)'	System	14 Oct 2020 19:30:11
	System	14 Oct 2020 19:30:11

US3012329

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:53:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-10-14T14:29:57', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '9b9de7f5-8a3e-4930-9749-b16cf7240aa1' User entered 'None (0)'	System	14 Oct 2020 19:30:11
	System	14 Oct 2020 19:30:11

US3012329

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:53:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-10-14T14:29:58', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '9b9de7f5-8a3e-4930-9749-b16cf7240aa1' User entered 'None (0)'	System	14 Oct 2020 19:30:11
	System	14 Oct 2020 19:30:11

US3012329

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:53:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-10-14T14:30:00', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '9b9de7f5-8a3e-4930-9749-b16cf7240aa1' User entered 'None (0)'	System	14 Oct 2020 19:30:11
	System	14 Oct 2020 19:30:11

US3012329

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:53:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-10-14T14:30:01', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '9b9de7f5-8a3e-4930-9749-b16cf7240aa1' User entered 'None (0)'	System	14 Oct 2020 19:30:11
	System	14 Oct 2020 19:30:11

US3012329

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:53:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-10-14T14:30:04', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '9b9de7f5-8a3e-4930-9749-b16cf7240aa1' User entered 'None (0)'	System	14 Oct 2020 19:30:11
	System	14 Oct 2020 19:30:11

US3012329

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:53:26

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)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-10-14T14:30:05', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '9b9de7f5-8a3e-4930-9749-b16cf7240aa1' User entered 'No (N)'	System	14 Oct 2020 19:30:11
	System	14 Oct 2020 19:30:11

US3012329

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:53:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-10-14T14:30:08', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '9b9de7f5-8a3e-4930-9749-b16cf7240aa1' User entered '14 Oct 2020 14:30'	System	14 Oct 2020 19:30:11
	System	14 Oct 2020 19:30:11

US3012329

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:53:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
User entered '14 Oct 2020 12:00'	System	13 Oct 2020 22:36:32

US3012329

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:53:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
User entered '15 Oct 2020 11:59'	System	13 Oct 2020 22:36:32

US3012329

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
Data entry locked.	System	13 Oct 2020 22:36:32
User entered 'Day 3'	System	13 Oct 2020 22:36:32

US3012329

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:53:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-10-15T12:17:04', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: 'b5ab4536-7038-4f6d-b43e-77fd57695820' User entered 'None (0)'	System	15 Oct 2020 17:17:53
	System	15 Oct 2020 17:17:53

US3012329

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:53:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-10-15T12:17:06', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: 'b5ab4536-7038-4f6d-b43e-77fd57695820' User entered 'None (0)'	System	15 Oct 2020 17:17:53
	System	15 Oct 2020 17:17:53

US3012329

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:53:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-10-15T12:17:07', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: 'b5ab4536-7038-4f6d-b43e-77fd57695820' User entered 'None (0)'	System	15 Oct 2020 17:17:53
	System	15 Oct 2020 17:17:53

US3012329

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:53:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-10-15T12:17:24', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: 'b5ab4536-7038-4f6d-b43e-77fd57695820' User entered 'None (0)'	System	15 Oct 2020 17:17:53
	System	15 Oct 2020 17:17:53

US3012329

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:53:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-10-15T12:17:25', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: 'b5ab4536-7038-4f6d-b43e-77fd57695820' User entered 'None (0)'	System	15 Oct 2020 17:17:53
	System	15 Oct 2020 17:17:53

US3012329

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:53:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-10-15T12:17:28', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: 'b5ab4536-7038-4f6d-b43e-77fd57695820' User entered 'None (0)'	System	15 Oct 2020 17:17:53
	System	15 Oct 2020 17:17:53

US3012329

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:53:26

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)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-10-15T12:17:31', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: 'b5ab4536-7038-4f6d-b43e-77fd57695820' User entered 'No (N)'	System	15 Oct 2020 17:17:53
	System	15 Oct 2020 17:17:53

US3012329

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:53:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-10-15T12:17:47', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: 'b5ab4536-7038-4f6d-b43e-77fd57695820' User entered '15 Oct 2020 12:17'	System	15 Oct 2020 17:17:53
	System	15 Oct 2020 17:17:53

US3012329

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:53:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
User entered '15 Oct 2020 12:00'	System	13 Oct 2020 22:36:32

US3012329

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:53:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
User entered '16 Oct 2020 11:59'	System	13 Oct 2020 22:36:32

US3012329

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
Data entry locked.	System	13 Oct 2020 22:36:32
User entered 'Day 4'	System	13 Oct 2020 22:36:32

US3012329

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:53:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-10-16T14:11:03', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '212fc27e-f526-448b-96ac-b7dc981652cd' User entered 'None (0)'	System	16 Oct 2020 19:11:30
	System	16 Oct 2020 19:11:30

US3012329

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:53:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-10-16T14:11:04', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '212fc27e-f526-448b-96ac-b7dc981652cd' User entered 'None (0)'	System	16 Oct 2020 19:11:30
	System	16 Oct 2020 19:11:30

US3012329

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:53:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-10-16T14:11:07', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '212fc27e-f526-448b-96ac-b7dc981652cd' User entered 'None (0)'	System	16 Oct 2020 19:11:30
	System	16 Oct 2020 19:11:30

US3012329

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:53:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-10-16T14:11:08', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '212fc27e-f526-448b-96ac-b7dc981652cd' User entered 'None (0)'	System	16 Oct 2020 19:11:30
	System	16 Oct 2020 19:11:30

US3012329

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:53:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-10-16T14:11:09', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '212fc27e-f526-448b-96ac-b7dc981652cd' User entered 'None (0)'	System	16 Oct 2020 19:11:30
	System	16 Oct 2020 19:11:30

US3012329

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:53:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-10-16T14:11:11', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '212fc27e-f526-448b-96ac-b7dc981652cd' User entered 'None (0)'	System	16 Oct 2020 19:11:30
	System	16 Oct 2020 19:11:30

US3012329

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:53:26

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)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-10-16T14:11:17', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '212fc27e-f526-448b-96ac-b7dc981652cd' User entered 'No (N)'	System	16 Oct 2020 19:11:30
	System	16 Oct 2020 19:11:30

US3012329

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:53:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-10-16T14:11:28', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '212fc27e-f526-448b-96ac-b7dc981652cd' User entered '16 Oct 2020 14:11'	System	16 Oct 2020 19:11:30
	System	16 Oct 2020 19:11:30

US3012329

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:53:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
User entered '16 Oct 2020 12:00'	System	13 Oct 2020 22:36:32

US3012329

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:53:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
User entered '17 Oct 2020 11:59'	System	13 Oct 2020 22:36:32

US3012329

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
Data entry locked.	System	13 Oct 2020 22:36:32
User entered 'Day 5'	System	13 Oct 2020 22:36:32

US3012329

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:53:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-10-17T19:53:22', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '670dab3a-f91e-4edb-9c94-38c6ee45538a' User entered 'None (0)'	System	18 Oct 2020 00:53:43
	System	18 Oct 2020 00:53:43

US3012329

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:53:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-10-17T19:53:23', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '670dab3a-f91e-4edb-9c94-38c6ee45538a' User entered 'None (0)'	System	18 Oct 2020 00:53:43
	System	18 Oct 2020 00:53:43

US3012329

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:53:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-10-17T19:53:25', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '670dab3a-f91e-4edb-9c94-38c6ee45538a' User entered 'None (0)'	System	18 Oct 2020 00:53:43
	System	18 Oct 2020 00:53:43

US3012329

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:53:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-10-17T19:53:27', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '670dab3a-f91e-4edb-9c94-38c6ee45538a' User entered 'None (0)'	System	18 Oct 2020 00:53:43
	System	18 Oct 2020 00:53:43

US3012329

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:53:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-10-17T19:53:30', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '670dab3a-f91e-4edb-9c94-38c6ee45538a' User entered 'None (0)'	System	18 Oct 2020 00:53:43
	System	18 Oct 2020 00:53:43

US3012329

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:53:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-10-17T19:53:32', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '670dab3a-f91e-4edb-9c94-38c6ee45538a' User entered 'None (0)'	System	18 Oct 2020 00:53:43
	System	18 Oct 2020 00:53:43

US3012329

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:53:26

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)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-10-17T19:53:34', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '670dab3a-f91e-4edb-9c94-38c6ee45538a' User entered 'No (N)'	System	18 Oct 2020 00:53:43
	System	18 Oct 2020 00:53:43

US3012329

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:53:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-10-17T19:53:37', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '670dab3a-f91e-4edb-9c94-38c6ee45538a' User entered '17 Oct 2020 19:53'	System	18 Oct 2020 00:53:43
	System	18 Oct 2020 00:53:43

US3012329

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:53:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
User entered '17 Oct 2020 12:00'	System	13 Oct 2020 22:36:32

US3012329

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:53:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
User entered '18 Oct 2020 11:59'	System	13 Oct 2020 22:36:32

US3012329

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
Data entry locked.	System	13 Oct 2020 22:36:32
User entered 'Day 6'	System	13 Oct 2020 22:36:32

US3012329

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:53:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-10-18T20:28:19', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: 'abf6fe2a-6b64-493f-a921-26c2d68b3f93' User entered 'None (0)'	System	19 Oct 2020 01:28:41
	System	19 Oct 2020 01:28:41

US3012329

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:53:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-10-18T20:28:22', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: 'abf6fe2a-6b64-493f-a921-26c2d68b3f93' User entered 'None (0)'	System	19 Oct 2020 01:28:41
	System	19 Oct 2020 01:28:41

US3012329

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:53:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-10-18T20:28:24', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: 'abf6fe2a-6b64-493f-a921-26c2d68b3f93' User entered 'None (0)'	System	19 Oct 2020 01:28:41
	System	19 Oct 2020 01:28:41

US3012329

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:53:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-10-18T20:28:27', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: 'abf6fe2a-6b64-493f-a921-26c2d68b3f93' User entered 'None (0)'	System	19 Oct 2020 01:28:41
	System	19 Oct 2020 01:28:41

US3012329

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:53:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-10-18T20:28:30', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: 'abf6fe2a-6b64-493f-a921-26c2d68b3f93' User entered 'None (0)'	System	19 Oct 2020 01:28:41
	System	19 Oct 2020 01:28:41

US3012329

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:53:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-10-18T20:28:32', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: 'abf6fe2a-6b64-493f-a921-26c2d68b3f93' User entered 'None (0)'	System	19 Oct 2020 01:28:41
	System	19 Oct 2020 01:28:41

US3012329

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:53:26

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)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-10-18T20:28:35', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: 'abf6fe2a-6b64-493f-a921-26c2d68b3f93'	System	19 Oct 2020 01:28:41
User entered 'No (N)'	System	19 Oct 2020 01:28:41

US3012329

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:53:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-10-18T20:28:38', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: 'abf6fe2a-6b64-493f-a921-26c2d68b3f93' User entered '18 Oct 2020 20:28'	System	19 Oct 2020 01:28:41
	System	19 Oct 2020 01:28:41

US3012329

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:53:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
User entered '18 Oct 2020 12:00'	System	13 Oct 2020 22:36:32

US3012329

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:53:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
User entered '19 Oct 2020 11:59'	System	13 Oct 2020 22:36:32

US3012329

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
Data entry locked.	System	13 Oct 2020 22:36:32
User entered 'Day 7'	System	13 Oct 2020 22:36:32

US3012329

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:53:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-10-19T12:02:24', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: 'f7b18146-951d-46b6-be10-7a1a635748af' User entered 'None (0)'	System	19 Oct 2020 17:02:45
	System	19 Oct 2020 17:02:45

US3012329

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:53:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-10-19T12:02:25', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: 'f7b18146-951d-46b6-be10-7a1a635748af' User entered 'None (0)'	System	19 Oct 2020 17:02:45
	System	19 Oct 2020 17:02:45

US3012329

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:53:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-10-19T12:02:27', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: 'f7b18146-951d-46b6-be10-7a1a635748af' User entered 'None (0)'	System	19 Oct 2020 17:02:45
	System	19 Oct 2020 17:02:45

US3012329

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:53:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-10-19T12:02:28', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: 'f7b18146-951d-46b6-be10-7a1a635748af' User entered 'None (0)'	System	19 Oct 2020 17:02:45
	System	19 Oct 2020 17:02:45

US3012329

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:53:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-10-19T12:02:29', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: 'f7b18146-951d-46b6-be10-7a1a635748af' User entered 'None (0)'	System	19 Oct 2020 17:02:45
	System	19 Oct 2020 17:02:45

US3012329

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:53:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-10-19T12:02:31', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: 'f7b18146-951d-46b6-be10-7a1a635748af' User entered 'None (0)'	System	19 Oct 2020 17:02:45
	System	19 Oct 2020 17:02:45

US3012329

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:53:26

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)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-10-19T12:02:33', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: 'f7b18146-951d-46b6-be10-7a1a635748af' User entered 'No (N)'	System	19 Oct 2020 17:02:45
	System	19 Oct 2020 17:02:45

US3012329

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:53:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-10-19T12:02:35', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: 'f7b18146-951d-46b6-be10-7a1a635748af' User entered '19 Oct 2020 12:02'	System	19 Oct 2020 17:02:45
	System	19 Oct 2020 17:02:45

US3012329

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:53:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
User entered '19 Oct 2020 12:00'	System	13 Oct 2020 22:36:32

US3012329

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:53:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
User entered '20 Oct 2020 11:59'	System	13 Oct 2020 22:36:32

US3012329

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:53:26

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered 'Yes (Y)'	Tambra Dora (b) (4)	20 Oct 2020 20:19:36

US3012329

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:53:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered '20 Oct 2020'	Tambra Dora (b) (4)	20 Oct 2020 20:19:36

US3012329

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:53:26

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered 'Contact Made (CONTACT MADE)'	Tambra Dora (b) (4)	20 Oct 2020 20:19:36

US3012329

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:53:26

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered empty.	(b) (4) Tambra Dora (b) (4) (b) (4)	20 Oct 2020 20:19:36

US3012329

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:53:26

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered 'Yes (Y)'	Tambra Dora (b) (4)	20 Oct 2020 20:19:40

US3012329

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:53:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User entered 'I'	System	20 Oct 2020 20:19:40

US3012329

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:53:26

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered 'Yes (Y)'	(b) (4) Katherine Davis (b) (4)	27 Oct 2020 15:47:11

US3012329

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:53:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered '27 Oct 2020'	Katherine Davis (b) (4)	27 Oct 2020 15:47:11

US3012329

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:53:26

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered 'Contact Made (CONTACT MADE)'	Katherine Davis (b) (4)	27 Oct 2020 15:47:11

US3012329

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:53:26

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered empty.	(b) (4) Katherine Davis (b) (4)	27 Oct 2020 15:47:11

US3012329

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:53:26

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered 'Yes (Y)'	Katherine Davis (b) (4)	27 Oct 2020 15:47:17

US3012329

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:53:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User entered 'I'	System	27 Oct 2020 15:47:17

US3012329

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:53:26

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered 'Yes (Y)'	(b) (4) Katherine Davis (b) (4)	03 Nov 2020 18:57:08

US3012329

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:53:26

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered '3 Nov 2020'	Katherine Davis (b) (4)	03 Nov 2020 18:57:08

US3012329

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:53:26

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered 'Contact Made (CONTACT MADE)'	Katherine Davis (b) (4)	03 Nov 2020 18:57:08

US3012329

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:53:26

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered empty.	(b) (4) Katherine Davis (b) (4)	03 Nov 2020 18:57:08

US3012329

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:53:26

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered 'Yes (Y)'	Katherine Davis (b) (4)	03 Nov 2020 18:57:14

US3012329

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:53:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User entered 'I'	System	03 Nov 2020 18:57:14

US3012329

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:53:26

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered 'Yes (Y)'	Lamar Box (b) (4)	13 Nov 2020 20:16:04

US3012329

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:53:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered '12 Nov 2020'	Lamar Box (b) (4)	13 Nov 2020 20:16:04

US3012329

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:53:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered 'Clinic (Clinic)'	Lamar Box (b) (4)	13 Nov 2020 20:16:04

US3012329

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:53:26

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User entered 'VISIT3'	System	13 Nov 2020 20:16:04

US3012329

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:53:26

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered 'Yes (Y)'	(b) (4) Lamar Box (b) (4) (b) (4)	13 Nov 2020 20:16:42

US3012329

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:53:26

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered '12 Nov 2020'	Lamar Box (b) (4)	13 Nov 2020 20:16:42

US3012329

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:53:26

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered '15:32'	Lamar Box (b) (4)	13 Nov 2020 20:16:42

US3012329

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:53:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User entered '12 Nov 2020 15:32'	System	13 Nov 2020 20:16:42

US3012329

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:53:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered '98.3' F	Lamar Box (b) (4)	13 Nov 2020 20:16:42

US3012329

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:53:26

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered 'Oral (Oral)'	Lamar Box (b) (4)	13 Nov 2020 20:16:42

US3012329

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:53:26

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered empty.	Lamar Box (b) (4)	13 Nov 2020 20:16:42

US3012329

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:53:26

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered '81'	Lamar Box (b) (4)	13 Nov 2020 20:16:42

US3012329

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:53:26

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User entered 'bpm'	System	13 Nov 2020 20:16:42

US3012329

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:53:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered '16'	Lamar Box (b) (4)	13 Nov 2020 20:16:42

US3012329

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:53:26

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User entered 'breaths/min'	System	13 Nov 2020 20:16:42

US3012329

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:53:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered '131'	Lamar Box (b) (4)	13 Nov 2020 20:16:42

US3012329

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:53:26

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User entered 'mmHg'	System	13 Nov 2020 20:16:42

US3012329

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:53:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered '82'	Lamar Box (b) (4)	13 Nov 2020 20:16:42

US3012329

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:53:26

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User entered 'mmHg'	System	13 Nov 2020 20:16:42

US3012329

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:53:26

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06

US3012329

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:53:26

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06

US3012329

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:53:26

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered 'No (N)'	Lamar Box (b) (4)	13 Nov 2020 20:17:10

US3012329

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:53:26

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered empty.	Lamar Box (b) (4)	13 Nov 2020 20:17:10

US3012329

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:53:26

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered 'Yes (Y)'	Lamar Box (b) (4)	13 Nov 2020 20:17:55

US3012329

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:53:26

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered '12 Nov 2020'	Lamar Box (b) (4)	13 Nov 2020 20:17:55

US3012329

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:53:26

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered '15:38'	Lamar Box (b) (4)	13 Nov 2020 20:17:55

US3012329

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:53:26

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User entered '12 Nov 2020 15:38'	System	13 Nov 2020 20:17:55

US3012329

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:53:26

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 21:11:10
User entered 'Yes (Y)'	Lamar Box (b) (4)	13 Nov 2020 20:18:00

US3012329

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:53:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User entered 'I'	System	13 Nov 2020 20:18:00

US3012329

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
Data entry locked.	System	15 Sep 2020 23:01:23
User entered 'Day 64'	System	15 Sep 2020 23:01:23

US3012329

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[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)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-11-17T12:01:22', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '6f4f86e1-45ad-489a-9e23-cef9d243b764'	System	17 Nov 2020 18:01:37
User entered 'No (N)'	System	17 Nov 2020 18:01:37

US3012329

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Have you been exposed to someone with 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)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-11-17T12:01:27', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '6f4f86e1-45ad-489a-9e23-cef9d243b764'	System	17 Nov 2020 18:01:37
User entered 'No (N)'	System	17 Nov 2020 18:01:37

US3012329

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-11-17T12:01:34', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '6f4f86e1-45ad-489a-9e23-cef9d243b764' User entered '17 Nov 2020 12:01:34'	System	17 Nov 2020 18:01:37
	System	17 Nov 2020 18:01:37

US3012329

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
Data entry locked.	System	15 Sep 2020 23:01:23
User entered '15 Nov 2020 00:01'	System	15 Sep 2020 23:01:23

US3012329

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:40:21
Data entry locked.	System	15 Sep 2020 23:01:23
User entered '19 Nov 2020 23:59'	System	15 Sep 2020 23:01:23

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[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 (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-11-22T00:01:59', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: 'f18ca61e-6dc6-4756-a24d-00a1428c97c8' User entered 'No (N)'	System	22 Nov 2020 06:02:13
	System	22 Nov 2020 06:02:13

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Have you been exposed to someone with 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 (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-11-22T00:02:03', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: 'f18ca61e-6dc6-4756-a24d-00a1428c97c8'	System	22 Nov 2020 06:02:13
User entered 'No (N)'	System	22 Nov 2020 06:02:13

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-11-22T00:02:07', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: 'f18ca61e-6dc6-4756-a24d-00a1428c97c8' User entered '22 Nov 2020 00:02:07'	System	22 Nov 2020 06:02:13
	System	22 Nov 2020 06:02:13

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '19 Nov 2020 00:01'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '23 Nov 2020 23:59'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[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 (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-11-27T17:56:32', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: 'e67c00ba-c8bc-4362-a528-8523d13cc3d1' User entered 'No (N)'	System	27 Nov 2020 23:56:40
	System	27 Nov 2020 23:56:40

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

Have you been exposed to someone with 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 (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-11-27T17:56:34', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: 'e67c00ba-c8bc-4362-a528-8523d13cc3d1' User entered 'No (N)'	System	27 Nov 2020 23:56:40

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-11-27T17:56:37', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: 'e67c00ba-c8bc-4362-a528-8523d13cc3d1' User entered '27 Nov 2020 17:56:37'	System	27 Nov 2020 23:56:40
	System	27 Nov 2020 23:56:40

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '26 Nov 2020 00:01'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '30 Nov 2020 23:59'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[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 (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-12-03T16:09:08', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '64e27727-9e3b-47b3-852e-6cae58fc58f3' User entered 'No (N)'	System	03 Dec 2020 22:09:19
	System	03 Dec 2020 22:09:19

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

Have you been exposed to someone with 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 (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-12-03T16:09:11', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '64e27727-9e3b-47b3-852e-6cae58fc58f3' User entered 'No (N)'	System	03 Dec 2020 22:09:19
	System	03 Dec 2020 22:09:19

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-12-03T16:09:15', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '64e27727-9e3b-47b3-852e-6cae58fc58f3' User entered '03 Dec 2020 16:09:15'	System	03 Dec 2020 22:09:19
	System	03 Dec 2020 22:09:19

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '03 Dec 2020 00:01'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '07 Dec 2020 23:59'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[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 (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-12-10T12:18:25', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '6088cc42-8120-4f83-b602-27f446b51765' User entered 'No (N)'	System	10 Dec 2020 18:18:33
	System	10 Dec 2020 18:18:33

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

Have you been exposed to someone with 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 (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-12-10T12:18:26', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '6088cc42-8120-4f83-b602-27f446b51765'	System	10 Dec 2020 18:18:33
User entered 'No (N)'	System	10 Dec 2020 18:18:33

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-12-10T12:18:30', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '6088cc42-8120-4f83-b602-27f446b51765' User entered '10 Dec 2020 12:18:30'	System	10 Dec 2020 18:18:33
	System	10 Dec 2020 18:18:33

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '10 Dec 2020 00:01'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '14 Dec 2020 23:59'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[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 (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-12-17T04:07:00', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '10b57a49-dea3-4357-b8a2-38e5496e1fb1' User entered 'No (N)'	System	17 Dec 2020 10:07:10
	System	17 Dec 2020 10:07:10

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Have you been exposed to someone with 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 (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-12-17T04:07:02', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '10b57a49-dea3-4357-b8a2-38e5496e1fb1' User entered 'No (N)'	System	17 Dec 2020 10:07:10
	System	17 Dec 2020 10:07:10

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-12-17T04:07:06', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '10b57a49-dea3-4357-b8a2-38e5496e1fb1' User entered '17 Dec 2020 04:07:06'	System	17 Dec 2020 10:07:10
	System	17 Dec 2020 10:07:10

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '17 Dec 2020 00:01'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '21 Dec 2020 23:59'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[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 (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-12-24T06:43:54', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: 'fe26eaf9-529b-4dbf-aaf3-e1ab743d0494' User entered 'No (N)'	System	24 Dec 2020 12:44:02
	System	24 Dec 2020 12:44:02

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

Have you been exposed to someone with 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 (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-12-24T06:43:55', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: 'fe26eaf9-529b-4dbf-aaf3-e1ab743d0494' User entered 'No (N)'	System	24 Dec 2020 12:44:02
	System	24 Dec 2020 12:44:02

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-12-24T06:43:59', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: 'fe26eaf9-529b-4dbf-aaf3-e1ab743d0494' User entered '24 Dec 2020 06:43:59'	System	24 Dec 2020 12:44:02
	System	24 Dec 2020 12:44:02

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '24 Dec 2020 00:01'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '28 Dec 2020 23:59'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[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 (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-12-31T06:31:48', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: 'a7ea02be-630d-4876-a5b4-6c0032121d4d' User entered 'No (N)'	System	31 Dec 2020 12:32:02
	System	31 Dec 2020 12:32:02

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Have you been exposed to someone with 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 (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-12-31T06:31:49', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: 'a7ea02be-630d-4876-a5b4-6c0032121d4d'	System	31 Dec 2020 12:32:02
User entered 'No (N)'	System	31 Dec 2020 12:32:02

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2020-12-31T06:31:59', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: 'a7ea02be-630d-4876-a5b4-6c0032121d4d' User entered '31 Dec 2020 06:31:59'	System	31 Dec 2020 12:32:02

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '31 Dec 2020 00:01'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '04 Jan 2021 23:59'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[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 (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2021-01-11T09:05:41', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '520cc068-0850-4139-8d5c-7c520c57148e' User entered 'No (N)'	System	11 Jan 2021 13:05:55
	System	11 Jan 2021 13:05:55

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Have you been exposed to someone with 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 (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2021-01-11T09:05:45', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '520cc068-0850-4139-8d5c-7c520c57148e' User entered 'No (N)'	System	11 Jan 2021 13:05:55
	System	11 Jan 2021 13:05:55

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2021-01-11T09:05:49', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '520cc068-0850-4139-8d5c-7c520c57148e' User entered '11 Jan 2021 09:05:49'	System	11 Jan 2021 13:05:55
	System	11 Jan 2021 13:05:55

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '07 Jan 2021 00:01'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '11 Jan 2021 23:59'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[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 (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2021-01-14T11:46:46', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '50ac2c23-59c7-4a54-a461-67c0b8d59947' User entered 'Yes (Y)'	System	14 Jan 2021 17:48:35
	System	14 Jan 2021 17:48:35

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Have you been exposed to someone with 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 (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2021-01-14T11:47:08', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '50ac2c23-59c7-4a54-a461-67c0b8d59947'	System	14 Jan 2021 17:48:35
User entered 'No (N)'	System	14 Jan 2021 17:48:35

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[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 (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2021-01-14T11:47:18', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '50ac2c23-59c7-4a54-a461-67c0b8d59947' User entered 'Yes (Y)'	System	14 Jan 2021 17:48:35
	System	14 Jan 2021 17:48:35

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2021-01-14T11:47:45', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '50ac2c23-59c7-4a54-a461-67c0b8d59947' User entered '0'	System	14 Jan 2021 17:48:35
	System	14 Jan 2021 17:48:35

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2021-01-14T11:47:45', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '50ac2c23-59c7-4a54-a461-67c0b8d59947' User entered '0'	System	14 Jan 2021 17:48:35

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2021-01-14T11:47:45', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '50ac2c23-59c7-4a54-a461-67c0b8d59947' User entered '1'	System	14 Jan 2021 17:48:35

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2021-01-14T11:47:45', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '50ac2c23-59c7-4a54-a461-67c0b8d59947' User entered '0'	System	14 Jan 2021 17:48:35
	System	14 Jan 2021 17:48:35

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2021-01-14T11:47:45', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '50ac2c23-59c7-4a54-a461-67c0b8d59947' User entered '0'	System	14 Jan 2021 17:48:35
	System	14 Jan 2021 17:48:35

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2021-01-14T11:47:45', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '50ac2c23-59c7-4a54-a461-67c0b8d59947' User entered '0'	System	14 Jan 2021 17:48:35

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2021-01-14T11:47:45', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '50ac2c23-59c7-4a54-a461-67c0b8d59947' User entered '0'	System	14 Jan 2021 17:48:35
	System	14 Jan 2021 17:48:35

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2021-01-14T11:47:45', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '50ac2c23-59c7-4a54-a461-67c0b8d59947' User entered '0'	System	14 Jan 2021 17:48:35
	System	14 Jan 2021 17:48:35

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2021-01-14T11:47:45', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '50ac2c23-59c7-4a54-a461-67c0b8d59947' User entered '1'	System	14 Jan 2021 17:48:35

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2021-01-14T11:47:45', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '50ac2c23-59c7-4a54-a461-67c0b8d59947' User entered '0'	System	14 Jan 2021 17:48:35
	System	14 Jan 2021 17:48:35

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2021-01-14T11:47:45', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '50ac2c23-59c7-4a54-a461-67c0b8d59947' User entered '0'	System	14 Jan 2021 17:48:35
	System	14 Jan 2021 17:48:35

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2021-01-14T11:47:45', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '50ac2c23-59c7-4a54-a461-67c0b8d59947' User entered '1'	System	14 Jan 2021 17:48:35

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2021-01-14T11:47:45', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '50ac2c23-59c7-4a54-a461-67c0b8d59947' User entered '0'	System	14 Jan 2021 17:48:35
	System	14 Jan 2021 17:48:35

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2021-01-14T11:47:45', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '50ac2c23-59c7-4a54-a461-67c0b8d59947' User entered '0'	System	14 Jan 2021 17:48:35
	System	14 Jan 2021 17:48:35

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2021-01-14T11:47:45', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '50ac2c23-59c7-4a54-a461-67c0b8d59947' User entered '0'	System	14 Jan 2021 17:48:35

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2021-01-14T11:47:45', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '50ac2c23-59c7-4a54-a461-67c0b8d59947' User entered '0'	System	14 Jan 2021 17:48:35
	System	14 Jan 2021 17:48:35

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2021-01-14T11:47:45', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '50ac2c23-59c7-4a54-a461-67c0b8d59947' User entered '0'	System	14 Jan 2021 17:48:35

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Please 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 (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2021-01-14T11:47:59', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '50ac2c23-59c7-4a54-a461-67c0b8d59947'	System	14 Jan 2021 17:48:35
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	14 Jan 2021 17:48:35

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[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 (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2021-01-14T11:48:21', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '50ac2c23-59c7-4a54-a461-67c0b8d59947'	System	14 Jan 2021 17:48:35
User entered 'No (N)'	System	14 Jan 2021 17:48:35

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2021-01-14T11:48:24', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '50ac2c23-59c7-4a54-a461-67c0b8d59947' User entered '14 Jan 2021 11:48:24'	System	14 Jan 2021 17:48:35
	System	14 Jan 2021 17:48:35

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '14 Jan 2021 00:01'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '18 Jan 2021 23:59'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[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 (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2021-01-24T16:17:16', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '36f85adc-6199-497d-b219-bb7ab9d887cd' User entered 'Yes (Y)'	System	24 Jan 2021 22:19:01
	System	24 Jan 2021 22:19:01

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

Have you been exposed to someone with 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 (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2021-01-24T16:17:22', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '36f85adc-6199-497d-b219-bb7ab9d887cd' User entered 'Yes (Y)'	System	24 Jan 2021 22:19:01
	System	24 Jan 2021 22:19:01

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Please 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 (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2021-01-24T16:17:42', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '36f85adc-6199-497d-b219-bb7ab9d887cd'	System	24 Jan 2021 22:19:01
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	24 Jan 2021 22:19:01

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[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 (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2021-01-24T16:17:49', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '36f85adc-6199-497d-b219-bb7ab9d887cd' User entered 'Yes (Y)'	System	24 Jan 2021 22:19:01
	System	24 Jan 2021 22:19:01

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2021-01-24T16:18:33', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '36f85adc-6199-497d-b219-bb7ab9d887cd' User entered '1'	System	24 Jan 2021 22:19:01

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2021-01-24T16:18:33', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '36f85adc-6199-497d-b219-bb7ab9d887cd' User entered '1'	System	24 Jan 2021 22:19:01

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2021-01-24T16:18:33', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '36f85adc-6199-497d-b219-bb7ab9d887cd' User entered '1'	System	24 Jan 2021 22:19:01

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2021-01-24T16:18:33', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '36f85adc-6199-497d-b219-bb7ab9d887cd' User entered '1'	System	24 Jan 2021 22:19:01
	System	24 Jan 2021 22:19:01

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2021-01-24T16:18:33', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '36f85adc-6199-497d-b219-bb7ab9d887cd' User entered '1'	System	24 Jan 2021 22:19:01

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2021-01-24T16:18:33', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '36f85adc-6199-497d-b219-bb7ab9d887cd' User entered '1'	System	24 Jan 2021 22:19:01

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2021-01-24T16:18:33', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '36f85adc-6199-497d-b219-bb7ab9d887cd' User entered '1'	System	24 Jan 2021 22:19:01
	System	24 Jan 2021 22:19:01

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2021-01-24T16:18:33', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '36f85adc-6199-497d-b219-bb7ab9d887cd' User entered '1'	System	24 Jan 2021 22:19:01

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2021-01-24T16:18:33', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '36f85adc-6199-497d-b219-bb7ab9d887cd' User entered '1'	System	24 Jan 2021 22:19:01

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2021-01-24T16:18:33', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '36f85adc-6199-497d-b219-bb7ab9d887cd' User entered '1'	System	24 Jan 2021 22:19:01

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2021-01-24T16:18:33', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '36f85adc-6199-497d-b219-bb7ab9d887cd' User entered '1'	System	24 Jan 2021 22:19:01

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2021-01-24T16:18:33', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '36f85adc-6199-497d-b219-bb7ab9d887cd' User entered '0'	System	24 Jan 2021 22:19:01
	System	24 Jan 2021 22:19:01

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2021-01-24T16:18:33', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '36f85adc-6199-497d-b219-bb7ab9d887cd' User entered '1'	System	24 Jan 2021 22:19:01

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2021-01-24T16:18:33', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '36f85adc-6199-497d-b219-bb7ab9d887cd' User entered '0'	System	24 Jan 2021 22:19:01
	System	24 Jan 2021 22:19:01

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2021-01-24T16:18:33', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '36f85adc-6199-497d-b219-bb7ab9d887cd' User entered '1'	System	24 Jan 2021 22:19:01

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2021-01-24T16:18:33', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '36f85adc-6199-497d-b219-bb7ab9d887cd' User entered '1'	System	24 Jan 2021 22:19:01

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2021-01-24T16:18:33', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '36f85adc-6199-497d-b219-bb7ab9d887cd' User entered '0'	System	24 Jan 2021 22:19:01

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Please 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 (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2021-01-24T16:18:38', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '36f85adc-6199-497d-b219-bb7ab9d887cd'	System	24 Jan 2021 22:19:01
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	24 Jan 2021 22:19:01

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[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 (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2021-01-24T16:18:44', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '36f85adc-6199-497d-b219-bb7ab9d887cd' User entered 'Yes (Y)'	System	24 Jan 2021 22:19:01
	System	24 Jan 2021 22:19:01

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Please 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 (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2021-01-24T16:18:49', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '36f85adc-6199-497d-b219-bb7ab9d887cd'	System	24 Jan 2021 22:19:01
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	24 Jan 2021 22:19:01

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2021-01-24T16:18:52', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '36f85adc-6199-497d-b219-bb7ab9d887cd' User entered '24 Jan 2021 16:18:52'	System	24 Jan 2021 22:19:01
	System	24 Jan 2021 22:19:01

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '21 Jan 2021 00:01'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '25 Jan 2021 23:59'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[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 (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2021-01-28T10:58:34', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '1ef9862a-7a66-4d70-b904-e9081b90c798' User entered 'Yes (Y)'	System	28 Jan 2021 16:59:53
	System	28 Jan 2021 16:59:53

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

Have you been exposed to someone with 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 (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2021-01-28T10:58:41', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '1ef9862a-7a66-4d70-b904-e9081b90c798'	System	28 Jan 2021 16:59:53
User entered 'Yes (Y)'	System	28 Jan 2021 16:59:53

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

Please 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 (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2021-01-28T10:58:50', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '1ef9862a-7a66-4d70-b904-e9081b90c798'	System	28 Jan 2021 16:59:53
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	28 Jan 2021 16:59:53

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[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 (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2021-01-28T10:59:01', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '1ef9862a-7a66-4d70-b904-e9081b90c798' User entered 'Yes (Y)'	System	28 Jan 2021 16:59:53
	System	28 Jan 2021 16:59:53

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2021-01-28T10:59:25', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '1ef9862a-7a66-4d70-b904-e9081b90c798'	System	28 Jan 2021 16:59:53
User entered '0'	System	28 Jan 2021 16:59:53

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2021-01-28T10:59:25', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '1ef9862a-7a66-4d70-b904-e9081b90c798'	System	28 Jan 2021 16:59:53
User entered '1'	System	28 Jan 2021 16:59:53

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2021-01-28T10:59:25', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '1ef9862a-7a66-4d70-b904-e9081b90c798'	System	28 Jan 2021 16:59:53
User entered '1'	System	28 Jan 2021 16:59:53

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2021-01-28T10:59:25', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '1ef9862a-7a66-4d70-b904-e9081b90c798' User entered '0'	System	28 Jan 2021 16:59:53
	System	28 Jan 2021 16:59:53

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2021-01-28T10:59:25', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '1ef9862a-7a66-4d70-b904-e9081b90c798'	System	28 Jan 2021 16:59:53
User entered '0'	System	28 Jan 2021 16:59:53

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2021-01-28T10:59:25', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '1ef9862a-7a66-4d70-b904-e9081b90c798'	System	28 Jan 2021 16:59:53
User entered '0'	System	28 Jan 2021 16:59:53

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2021-01-28T10:59:25', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '1ef9862a-7a66-4d70-b904-e9081b90c798'	System	28 Jan 2021 16:59:53
User entered '0'	System	28 Jan 2021 16:59:53

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2021-01-28T10:59:25', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '1ef9862a-7a66-4d70-b904-e9081b90c798'	System	28 Jan 2021 16:59:53
User entered '1'	System	28 Jan 2021 16:59:53

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2021-01-28T10:59:25', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '1ef9862a-7a66-4d70-b904-e9081b90c798'	System	28 Jan 2021 16:59:53
User entered '1'	System	28 Jan 2021 16:59:53

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2021-01-28T10:59:25', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '1ef9862a-7a66-4d70-b904-e9081b90c798'	System	28 Jan 2021 16:59:53
User entered '0'	System	28 Jan 2021 16:59:53

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2021-01-28T10:59:25', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '1ef9862a-7a66-4d70-b904-e9081b90c798'	System	28 Jan 2021 16:59:53
User entered '0'	System	28 Jan 2021 16:59:53

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2021-01-28T10:59:25', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '1ef9862a-7a66-4d70-b904-e9081b90c798'	System	28 Jan 2021 16:59:53
User entered '0'	System	28 Jan 2021 16:59:53

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2021-01-28T10:59:25', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '1ef9862a-7a66-4d70-b904-e9081b90c798'	System	28 Jan 2021 16:59:53
User entered '0'	System	28 Jan 2021 16:59:53

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2021-01-28T10:59:25', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '1ef9862a-7a66-4d70-b904-e9081b90c798' User entered '0'	System	28 Jan 2021 16:59:53
	System	28 Jan 2021 16:59:53

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2021-01-28T10:59:25', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '1ef9862a-7a66-4d70-b904-e9081b90c798'	System	28 Jan 2021 16:59:53
User entered '1'	System	28 Jan 2021 16:59:53

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2021-01-28T10:59:25', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '1ef9862a-7a66-4d70-b904-e9081b90c798'	System	28 Jan 2021 16:59:53
User entered '0'	System	28 Jan 2021 16:59:53

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2021-01-28T10:59:25', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '1ef9862a-7a66-4d70-b904-e9081b90c798'	System	28 Jan 2021 16:59:53
User entered '0'	System	28 Jan 2021 16:59:53

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Please 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 (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2021-01-28T10:59:28', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '1ef9862a-7a66-4d70-b904-e9081b90c798'	System	28 Jan 2021 16:59:53
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	28 Jan 2021 16:59:53

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[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 (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2021-01-28T10:59:36', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '1ef9862a-7a66-4d70-b904-e9081b90c798' User entered 'Yes (Y)'	System	28 Jan 2021 16:59:53
	System	28 Jan 2021 16:59:53

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Please 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 (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2021-01-28T10:59:39', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '1ef9862a-7a66-4d70-b904-e9081b90c798'	System	28 Jan 2021 16:59:53
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	28 Jan 2021 16:59:53

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2021-01-28T10:59:43', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '1ef9862a-7a66-4d70-b904-e9081b90c798' User entered '28 Jan 2021 10:59:43'	System	28 Jan 2021 16:59:53
	System	28 Jan 2021 16:59:53

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '28 Jan 2021 00:01'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '01 Feb 2021 23:59'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[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 (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2021-02-04T08:02:56', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '2314b0ad-ba62-466f-b65b-eb89e9c087c6' User entered 'No (N)'	System	04 Feb 2021 14:03:26
	System	04 Feb 2021 14:03:26

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

Have you been exposed to someone with 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 (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2021-02-04T08:03:07', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '2314b0ad-ba62-466f-b65b-eb89e9c087c6' User entered 'Yes (Y)'	System	04 Feb 2021 14:03:26
	System	04 Feb 2021 14:03:26

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

Please 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 (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2021-02-04T08:03:12', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '2314b0ad-ba62-466f-b65b-eb89e9c087c6'	System	04 Feb 2021 14:03:26
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	04 Feb 2021 14:03:26

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2021-02-04T08:03:15', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '2314b0ad-ba62-466f-b65b-eb89e9c087c6' User entered '04 Feb 2021 08:03:15'	System	04 Feb 2021 14:03:26
	System	04 Feb 2021 14:03:26

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '04 Feb 2021 00:01'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '08 Feb 2021 23:59'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[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 (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2021-02-11T17:11:57', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '3f849399-f1c2-4fb2-bbe5-5ad7c2e465f2'	System	11 Feb 2021 23:16:56
User entered 'No (N)'	System	11 Feb 2021 23:16:56

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Have you been exposed to someone with 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 (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2021-02-11T17:12:03', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '3f849399-f1c2-4fb2-bbe5-5ad7c2e465f2'	System	11 Feb 2021 23:16:56
User entered 'No (N)'	System	11 Feb 2021 23:16:56

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2021-02-11T17:12:06', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '3f849399-f1c2-4fb2-bbe5-5ad7c2e465f2' User entered '11 Feb 2021 17:12:06'	System	11 Feb 2021 23:16:56
	System	11 Feb 2021 23:16:56

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '11 Feb 2021 00:01'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '15 Feb 2021 23:59'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[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 (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2021-02-18T00:01:20', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '51934a12-951a-4b94-8238-8f5b9b481cf2' User entered 'No (N)'	System	18 Feb 2021 06:01:48
	System	18 Feb 2021 06:01:48

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

Have you been exposed to someone with 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 (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2021-02-18T00:01:24', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '51934a12-951a-4b94-8238-8f5b9b481cf2'	System	18 Feb 2021 06:01:48
User entered 'No (N)'	System	18 Feb 2021 06:01:48

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2021-02-18T00:01:27', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '51934a12-951a-4b94-8238-8f5b9b481cf2' User entered '18 Feb 2021 00:01:27'	System	18 Feb 2021 06:01:48
	System	18 Feb 2021 06:01:48

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '18 Feb 2021 00:01'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '22 Feb 2021 23:59'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[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 (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2021-02-25T14:37:21-06:00', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '4c249940-5fbd-41d9-969c-bdb368e97d24'	System	25 Feb 2021 20:37:38
User entered 'No (N)'	System	25 Feb 2021 20:37:38

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

Have you been exposed to someone with 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 (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2021-02-25T14:37:26-06:00', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '4c249940-5fbd-41d9-969c-bdb368e97d24'	System	25 Feb 2021 20:37:38
User entered 'No (N)'	System	25 Feb 2021 20:37:38

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2021-02-25T14:37:31-06:00', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '4c249940-5fbd-41d9-969c-bdb368e97d24'	System	25 Feb 2021 20:37:38
User entered '25 Feb 2021 20:37:31'	System	25 Feb 2021 20:37:38

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '25 Feb 2021 00:01'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '01 Mar 2021 23:59'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[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 (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2021-03-04T10:46:59-06:00', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '1ae9f9d2-f80d-4e40-abc1-f46c0df4639a' User entered 'Yes (Y)'	System	04 Mar 2021 16:47:51
	System	04 Mar 2021 16:47:51

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Have you been exposed to someone with 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 (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2021-03-04T10:47:21-06:00', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '1ae9f9d2-f80d-4e40-abc1-f46c0df4639a' User entered 'No (N)'	System	04 Mar 2021 16:47:51

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[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 (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2021-03-04T10:47:30-06:00', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '1ae9f9d2-f80d-4e40-abc1-f46c0df4639a' User entered 'No (N)'	System	04 Mar 2021 16:47:51
	System	04 Mar 2021 16:47:51

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[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 (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2021-03-04T10:47:42-06:00', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '1ae9f9d2-f80d-4e40-abc1-f46c0df4639a' User entered 'No (N)'	System	04 Mar 2021 16:47:51
	System	04 Mar 2021 16:47:51

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2021-03-04T10:47:45-06:00', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '1ae9f9d2-f80d-4e40-abc1-f46c0df4639a' User entered '04 Mar 2021 10:47:45'	System	04 Mar 2021 16:47:51
	System	04 Mar 2021 16:47:51

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '04 Mar 2021 00:01'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '08 Mar 2021 23:59'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[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 (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2021-03-11T04:11:18-06:00', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: 'cfcda56b-ce5b-499b-8761-948ab2d6f0c4'	System	11 Mar 2021 10:11:42
User entered 'No (N)'	System	11 Mar 2021 10:11:42

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

Have you been exposed to someone with 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 (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2021-03-11T04:11:23-06:00', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: 'cfcda56b-ce5b-499b-8761-948ab2d6f0c4'	System	11 Mar 2021 10:11:42
User entered 'No (N)'	System	11 Mar 2021 10:11:42

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2021-03-11T04:11:26-06:00', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: 'cfcda56b-ce5b-499b-8761-948ab2d6f0c4' User entered '11 Mar 2021 04:11:26'	System	11 Mar 2021 10:11:42
	System	11 Mar 2021 10:11:42

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '11 Mar 2021 00:01'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '15 Mar 2021 23:59'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[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 (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2021-03-18T09:36:11-05:00', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: 'ced1a808-3e3b-410e-8ce6-c9e77df26cd9'	System	18 Mar 2021 14:36:24
User entered 'No (N)'	System	18 Mar 2021 14:36:24

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Have you been exposed to someone with 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 (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2021-03-18T09:36:15-05:00', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: 'ced1a808-3e3b-410e-8ce6-c9e77df26cd9'	System	18 Mar 2021 14:36:24
User entered 'No (N)'	System	18 Mar 2021 14:36:24

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2021-03-18T09:36:20-05:00', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: 'ced1a808-3e3b-410e-8ce6-c9e77df26cd9' User entered '18 Mar 2021 09:36:20'	System	18 Mar 2021 14:36:24
	System	18 Mar 2021 14:36:24

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '18 Mar 2021 00:01'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '22 Mar 2021 23:59'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[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 (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2021-03-25T12:52:38-05:00', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: 'b635de07-9385-4afa-823e-c72206dec647'	System	25 Mar 2021 17:52:55
User entered 'No (N)'	System	25 Mar 2021 17:52:55

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

Have you been exposed to someone with 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 (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2021-03-25T12:52:47-05:00', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: 'b635de07-9385-4afa-823e-c72206dec647'	System	25 Mar 2021 17:52:55
User entered 'No (N)'	System	25 Mar 2021 17:52:55

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2021-03-25T12:52:50-05:00', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: 'b635de07-9385-4afa-823e-c72206dec647'	System	25 Mar 2021 17:52:55
User entered '25 Mar 2021 12:52:50'	System	25 Mar 2021 17:52:55

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '25 Mar 2021 00:01'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '29 Mar 2021 23:59'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[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 (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2021-04-01T08:13:05-05:00', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: 'bf30435d-c657-4554-acac-6ab763fc5380'	System	01 Apr 2021 13:13:14
User entered 'No (N)'	System	01 Apr 2021 13:13:14

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

Have you been exposed to someone with 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 (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2021-04-01T08:13:07-05:00', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: 'bf30435d-c657-4554-acac-6ab763fc5380'	System	01 Apr 2021 13:13:14
User entered 'No (N)'	System	01 Apr 2021 13:13:14

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2021-04-01T08:13:10-05:00', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: 'bf30435d-c657-4554-acac-6ab763fc5380'	System	01 Apr 2021 13:13:14
User entered '01 Apr 2021 08:13:10'	System	01 Apr 2021 13:13:14

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '01 Apr 2021 00:01'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '05 Apr 2021 23:59'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[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 (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2021-04-08T00:37:57-05:00', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: 'd62d5fe9-e552-43e6-8534-0bf8dd22bdcdb' User entered 'No (N)'	System	08 Apr 2021 05:38:06
	System	08 Apr 2021 05:38:06

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

Have you been exposed to someone with 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 (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2021-04-08T00:37:59-05:00', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: 'd62d5fe9-e552-43e6-8534-0bf8dd22bdc b' User entered 'No (N)'	System	08 Apr 2021 05:38:06

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2021-04-08T00:38:02-05:00', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: 'd62d5fe9-e552-43e6-8534-0bf8dd22bdcdb' User entered '08 Apr 2021 00:38:02'	System	08 Apr 2021 05:38:06
	System	08 Apr 2021 05:38:06

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '08 Apr 2021 00:01'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '12 Apr 2021 23:59'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[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 (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2021-04-15T00:06:32-05:00', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: 'cf5cd65f-ea9b-48f0-981f-49d09b775db9'	System	15 Apr 2021 05:07:16
User entered 'No (N)'	System	15 Apr 2021 05:07:16

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

Have you been exposed to someone with 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 (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2021-04-15T00:06:38-05:00', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: 'cf5cd65f-ea9b-48f0-981f-49d09b775db9'	System	15 Apr 2021 05:07:16
User entered 'No (N)'	System	15 Apr 2021 05:07:16

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2021-04-15T00:07:13-05:00', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: 'cf5cd65f-ea9b-48f0-981f-49d09b775db9'	System	15 Apr 2021 05:07:16
User entered '15 Apr 2021 00:07:13'	System	15 Apr 2021 05:07:16

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '15 Apr 2021 00:01'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '19 Apr 2021 23:59'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[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 (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2021-04-22T00:18:48-05:00', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: 'd8774184-2b67-4b99-9797-c2afa215693e' User entered 'No (N)'	System	22 Apr 2021 05:18:58
	System	22 Apr 2021 05:18:58

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

Have you been exposed to someone with 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 (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2021-04-22T00:18:51-05:00', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: 'd8774184-2b67-4b99-9797-c2afa215693e'	System	22 Apr 2021 05:18:58
User entered 'No (N)'	System	22 Apr 2021 05:18:58

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2021-04-22T00:18:54-05:00', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: 'd8774184-2b67-4b99-9797-c2afa215693e'	System	22 Apr 2021 05:18:58
User entered '22 Apr 2021 00:18:54'	System	22 Apr 2021 05:18:58

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '22 Apr 2021 00:01'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '26 Apr 2021 23:59'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[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 (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2021-04-30T08:04:48-05:00', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: 'fca9b870-101a-4a23-8058-2402a731703a' User entered 'No (N)'	System	30 Apr 2021 13:04:56
	System	30 Apr 2021 13:04:56

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

Have you been exposed to someone with 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 (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2021-04-30T08:04:50-05:00', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: 'fca9b870-101a-4a23-8058-2402a731703a' User entered 'No (N)'	System	30 Apr 2021 13:04:56

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2021-04-30T08:04:53-05:00', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: 'fca9b870-101a-4a23-8058-2402a731703a' User entered '30 Apr 2021 08:04:53'	System	30 Apr 2021 13:04:56
	System	30 Apr 2021 13:04:56

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '29 Apr 2021 00:01'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '03 May 2021 23:59'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '06 May 2021 00:01'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '10 May 2021 23:59'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '13 May 2021 00:01'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '17 May 2021 23:59'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '20 May 2021 00:01'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '24 May 2021 23:59'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '27 May 2021 00:01'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '31 May 2021 23:59'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '03 Jun 2021 00:01'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '07 Jun 2021 23:59'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '10 Jun 2021 00:01'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '14 Jun 2021 23:59'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '17 Jun 2021 00:01'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '21 Jun 2021 23:59'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '24 Jun 2021 00:01'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '28 Jun 2021 23:59'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '01 Jul 2021 00:01'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '05 Jul 2021 23:59'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '08 Jul 2021 00:01'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '12 Jul 2021 23:59'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '15 Jul 2021 00:01'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '19 Jul 2021 23:59'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '22 Jul 2021 00:01'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '26 Jul 2021 23:59'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '29 Jul 2021 00:01'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '02 Aug 2021 23:59'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '05 Aug 2021 00:01'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '09 Aug 2021 23:59'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '12 Aug 2021 00:01'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '16 Aug 2021 23:59'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '19 Aug 2021 00:01'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '23 Aug 2021 23:59'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '26 Aug 2021 00:01'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '30 Aug 2021 23:59'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '02 Sep 2021 00:01'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '06 Sep 2021 23:59'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '09 Sep 2021 00:01'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '13 Sep 2021 23:59'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '16 Sep 2021 00:01'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '20 Sep 2021 23:59'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '23 Sep 2021 00:01'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '27 Sep 2021 23:59'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '30 Sep 2021 00:01'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '04 Oct 2021 23:59'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '07 Oct 2021 00:01'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '11 Oct 2021 23:59'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '14 Oct 2021 00:01'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '18 Oct 2021 23:59'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '21 Oct 2021 00:01'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '25 Oct 2021 23:59'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '28 Oct 2021 00:01'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '01 Nov 2021 23:59'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '04 Nov 2021 00:01'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '08 Nov 2021 23:59'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '11 Nov 2021 00:01'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '15 Nov 2021 23:59'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '18 Nov 2021 00:01'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '22 Nov 2021 23:59'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '25 Nov 2021 00:01'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '29 Nov 2021 23:59'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '02 Dec 2021 00:01'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '06 Dec 2021 23:59'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '09 Dec 2021 00:01'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '13 Dec 2021 23:59'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '16 Dec 2021 00:01'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '20 Dec 2021 23:59'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '23 Dec 2021 00:01'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '27 Dec 2021 23:59'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '30 Dec 2021 00:01'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '03 Jan 2022 23:59'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '06 Jan 2022 00:01'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '10 Jan 2022 23:59'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '13 Jan 2022 00:01'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '17 Jan 2022 23:59'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '20 Jan 2022 00:01'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '24 Jan 2022 23:59'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '27 Jan 2022 00:01'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '31 Jan 2022 23:59'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '03 Feb 2022 00:01'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '07 Feb 2022 23:59'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '10 Feb 2022 00:01'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '14 Feb 2022 23:59'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '17 Feb 2022 00:01'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '21 Feb 2022 23:59'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '24 Feb 2022 00:01'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '28 Feb 2022 23:59'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '03 Mar 2022 00:01'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '07 Mar 2022 23:59'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '10 Mar 2022 00:01'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '14 Mar 2022 23:59'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '17 Mar 2022 00:01'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '21 Mar 2022 23:59'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '24 Mar 2022 00:01'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '28 Mar 2022 23:59'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '31 Mar 2022 00:01'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '04 Apr 2022 23:59'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '07 Apr 2022 00:01'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '11 Apr 2022 23:59'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '14 Apr 2022 00:01'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '18 Apr 2022 23:59'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '21 Apr 2022 00:01'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '25 Apr 2022 23:59'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '28 Apr 2022 00:01'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '02 May 2022 23:59'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '05 May 2022 00:01'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '09 May 2022 23:59'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '12 May 2022 00:01'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '16 May 2022 23:59'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '19 May 2022 00:01'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '23 May 2022 23:59'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '26 May 2022 00:01'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '30 May 2022 23:59'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '02 Jun 2022 00:01'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '06 Jun 2022 23:59'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '09 Jun 2022 00:01'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '13 Jun 2022 23:59'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '16 Jun 2022 00:01'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '20 Jun 2022 23:59'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '23 Jun 2022 00:01'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '27 Jun 2022 23:59'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '30 Jun 2022 00:01'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '04 Jul 2022 23:59'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '07 Jul 2022 00:01'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '11 Jul 2022 23:59'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '14 Jul 2022 00:01'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '18 Jul 2022 23:59'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '21 Jul 2022 00:01'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '25 Jul 2022 23:59'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '28 Jul 2022 00:01'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '01 Aug 2022 23:59'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '04 Aug 2022 00:01'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '08 Aug 2022 23:59'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '11 Aug 2022 00:01'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '15 Aug 2022 23:59'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '18 Aug 2022 00:01'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '22 Aug 2022 23:59'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '25 Aug 2022 00:01'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '29 Aug 2022 23:59'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '01 Sep 2022 00:01'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '05 Sep 2022 23:59'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '08 Sep 2022 00:01'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '12 Sep 2022 23:59'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '15 Sep 2022 00:01'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '19 Sep 2022 23:59'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '22 Sep 2022 00:01'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '26 Sep 2022 23:59'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '29 Sep 2022 00:01'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '03 Oct 2022 23:59'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '06 Oct 2022 00:01'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '10 Oct 2022 23:59'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '13 Oct 2022 00:01'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '17 Oct 2022 23:59'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '20 Oct 2022 00:01'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '24 Oct 2022 23:59'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '27 Oct 2022 00:01'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '31 Oct 2022 23:59'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '03 Nov 2022 00:01'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '07 Nov 2022 23:59'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '10 Nov 2022 00:01'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '14 Nov 2022 23:59'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '17 Nov 2022 00:01'	System	20 Nov 2020 08:47:32

US3012329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:32
Amendment Manager: User entered '21 Nov 2022 23:59'	System	20 Nov 2020 08:47:32

US3012329

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 21:53:26

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:52:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2021-02-27T19:20:42-06:00', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '1fc1d92d-f453-4e89-aa28-f6121608a96a'	System	28 Feb 2021 01:21:25
User entered 'No (N)'	System	28 Feb 2021 01:21:25

US3012329

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 21:53:26

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:52:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30048914-DC8E-4974-A333-1FD4996EDFD4)', Time: '2021-02-27T19:20:52-06:00', User OID: 'PatientReportedOutcome (US3012329)', ODM File OID: '1fc1d92d-f453-4e89-aa28-f6121608a96a' User entered '28 Feb 2021 01:20:52'	System	28 Feb 2021 01:21:25
	System	28 Feb 2021 01:21:25

US3012329

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:53:26

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User signature succeeded.	Laurence Chu (b) (4)	05 Mar 2021 19:36:43
User entered 'Yes (Y)' reason for change: Data Entry Error	Jessica Ruff (b) (4)	09 Dec 2020 00:28:57
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	17 Nov 2020 06:31:30
Query 'Data is required. Please complete.' answered with 'Initial data entered in error. Correct data will be entered when even has occurred.' (Site from System).	Lamar Box (b) (4)	13 Nov 2020 20:21:55
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Nov 2020 20:21:22
User entered empty; reason for change Data Entry Error	Lamar Box (b) (4)	13 Nov 2020 20:21:22
User entered 'Yes (Y)'	Lamar Box (b) (4)	13 Nov 2020 20:19:34

US3012329

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:53:26

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User signature succeeded.	Laurence Chu (b) (4)	05 Mar 2021 19:36:43
User entered '8 Dec 2020' reason for change: Data Entry Error	Jessica Ruff (b) (4)	09 Dec 2020 00:28:57
User closed query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4), (b) (6)	17 Nov 2020 06:31:34
User entered empty; reason for change Data Entry Error	Lamar Box (b) (4)	13 Nov 2020 20:21:22
Query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'Data correct as entered.' (Site from System).	Lamar Box (b) (4)	13 Nov 2020 20:19:58
User opened query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	13 Nov 2020 20:19:34
User entered '12 Nov 2020'	Lamar Box (b) (4)	13 Nov 2020 20:19:34

US3012329

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:53:26

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User signature succeeded.	Laurence Chu (b) (4)	05 Mar 2021 19:36:43
User entered 'Contact Made (CONTACT MADE)'	Jessica Ruff (b) (4)	09 Dec 2020 00:28:57
reason for change: Data Entry Error	(b) (4)	
User entered empty; reason for change Data Entry Error	Lamar Box (b) (4)	13 Nov 2020 20:21:22
User entered 'Contact Made (CONTACT MADE)'	Lamar Box (b) (4)	13 Nov 2020 20:19:34

US3012329

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:53:26

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User signature succeeded.	Laurence Chu (b) (4)	05 Mar 2021 19:36:43
User entered empty.	(b) (4) Lamar Box (b) (4) (b) (4)	13 Nov 2020 20:19:34

US3012329

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:53:26

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User signature succeeded.	Laurence Chu (b) (4)	05 Mar 2021 19:36:43
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	09 Dec 2020 00:29:01
User closed query 'Data is required. Please complete.' (Site from System).	Jessica Ruff (b) (4)	09 Dec 2020 00:29:01
Query 'Data is required. Please complete.' answered with 'Data entered in error. Appropriate data will be entered when event occurs.' (Site from System).	(b) (4)	17 Nov 2020 06:31:39
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	17 Nov 2020 06:31:39
User entered empty; reason for change Data Entry Error	Lamar Box (b) (4)	13 Nov 2020 20:23:42
User entered 'Yes (Y)'	(b) (4)	13 Nov 2020 20:23:42
	System	13 Nov 2020 20:20:56
	Lamar Box (b) (4)	13 Nov 2020 20:20:56
	(b) (4)	13 Nov 2020 20:20:56
	Lamar Box (b) (4)	13 Nov 2020 20:20:09
	(b) (4)	13 Nov 2020 20:20:09

US3012329

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:53:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:32:06
User entered '1'	System	09 Dec 2020 00:29:01
User entered empty.	System	13 Nov 2020 20:20:56
User entered '1'	System	13 Nov 2020 20:20:09

US3012329

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:53:26

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:40:44
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered 'Yes (Y)'	Jessica Ruff (b) (4)	12 Jan 2021 18:02:29

US3012329

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:53:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:40:44
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered '12 Jan 2021'	Jessica Ruff (b) (4)	12 Jan 2021 18:02:29

US3012329

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:53:26

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:40:44
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered 'Contact Made (CONTACT MADE)'	Jessica Ruff (b) (4)	12 Jan 2021 18:02:29

US3012329

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:53:26

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:40:44
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered empty.	Jessica Ruff (b) (4)	12 Jan 2021 18:02:29

US3012329

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:53:26

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:40:44
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered 'Yes (Y)'	Jessica Ruff (b) (4)	12 Jan 2021 18:02:44

US3012329

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:53:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:40:44
User entered 'I'	System	12 Jan 2021 18:02:44

US3012329

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:53:26

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:40:44
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:08
User entered 'Yes (Y)'	Jessica Ruff (b) (4)	12 Feb 2021 19:39:45

US3012329

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:53:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:40:44
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:08
User entered '12 Feb 2021'	Jessica Ruff (b) (4)	12 Feb 2021 19:39:45

US3012329

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:53:26

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:40:44
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:08
User entered 'Contact Made (CONTACT MADE)'	Jessica Ruff (b) (4)	12 Feb 2021 19:39:45

US3012329

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:53:26

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:40:44
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:08
User entered empty.	Jessica Ruff (b) (4)	12 Feb 2021 19:39:45

US3012329

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:53:26

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:40:44
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered 'Yes (Y)'	Jessica Ruff (b) (4)	12 Feb 2021 19:39:48

US3012329

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:53:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:40:44
User entered '1'	System	12 Feb 2021 19:39:48

US3012329

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:53:26

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:40:44
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:08
User entered 'Yes (Y)'	(b) (4)	11 Mar 2021 17:14:53
	(b) (4), (b) (6)	

US3012329

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:53:26

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:40:44
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:08
User entered '11 Mar 2021'	(b) (4), (b) (6)	11 Mar 2021 17:14:53

US3012329

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:53:26

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:40:44
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:08
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 17:14:53

US3012329

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:53:26

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:40:44
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:08
User entered empty.	(b) (4), (b) (6)	11 Mar 2021 17:14:53

US3012329

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:53:26

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:40:44
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:08
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 17:14:58

US3012329

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:53:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:40:44
User entered 'I'	System	11 Mar 2021 17:14:58

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: COVID-19 Contact

Generated On: 11 Aug 2021 21:53:26

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:41
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:42:00
User entered '12 Jan 2021'	Jennifer Leyva (b) (4) (b) (4)	14 Jan 2021 20:05:01

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: COVID-19 Contact

Generated On: 11 Aug 2021 21:53:26

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:41
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:42:00
User entered '11:33'	Jennifer Leyva (b) (4) (b) (4)	14 Jan 2021 20:05:01

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: COVID-19 Contact

Generated On: 11 Aug 2021 21:53:26

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:41
User entered '12 Jan 2021 11:33'	System	14 Jan 2021 20:05:01

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: COVID-19 Contact

Generated On: 11 Aug 2021 21:53:26

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:41
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:42:00
User entered 'Safety Call (Safety Call)'	Jennifer Leyva (b) (4) (b) (4)	14 Jan 2021 20:05:01

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: COVID-19 Contact

Generated On: 11 Aug 2021 21:53:26

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:41
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:00
User entered 'Yes (Y)'	Jennifer Leyva (b) (4)	14 Jan 2021 20:05:01

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:53:26

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered 'Day 1 (Day 1)'	Jennifer Leyva (b) (4)	14 Jan 2021 20:06:51

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:53:26

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered '11 Jan 2021'	Jennifer Leyva (b) (4) (b) (4)	14 Jan 2021 20:06:51

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:53:26

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	14 Jan 2021 20:06:51

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:53:26

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered missing code ND - Not Done.	Jennifer Leyva (b) (4) (b) (4)	14 Jan 2021 20:06:51

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:53:26

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User entered '%'	System	14 Jan 2021 20:06:51

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:53:26

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered missing code ND - Not Done.	Jennifer Leyva (b) (4) (b) (4)	14 Jan 2021 20:06:51

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:53:26

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'None (None)'	Jennifer Leyva (b) (4) (b) (4)	14 Jan 2021 20:06:51

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:53:26

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'Mild (Mild)'	Jennifer Leyva (b) (4) (b) (4)	14 Jan 2021 20:06:51

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:53:26

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'None (None)'	Jennifer Leyva (b) (4) (b) (4)	14 Jan 2021 20:06:51

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:53:26

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'None (None)'	Jennifer Leyva (b) (4) (b) (4)	14 Jan 2021 20:06:51

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:53:26

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'None (None)'	Jennifer Leyva (b) (4)	14 Jan 2021 20:06:51

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:53:26

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'None (None)'	Jennifer Leyva (b) (4) (b) (4)	14 Jan 2021 20:06:51

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:53:26

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'Moderate (Moderate)'	Jennifer Leyva (b) (4) (b) (4)	14 Jan 2021 20:06:51

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:53:26

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'Moderate (Moderate)'	Jennifer Leyva (b) (4) (b) (4)	14 Jan 2021 20:06:51

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:53:26

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'None (None)'	Jennifer Leyva (b) (4) (b) (4)	14 Jan 2021 20:06:51

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:53:26

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'None (None)'	Jennifer Leyva (b) (4)	14 Jan 2021 20:06:51

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:53:26

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'None (None)'	Jennifer Leyva (b) (4)	14 Jan 2021 20:06:51

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:53:26

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'None (None)'	Jennifer Leyva (b) (4)	14 Jan 2021 20:06:51

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:53:26

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'None (None)'	Jennifer Leyva (b) (4) (b) (4)	14 Jan 2021 20:06:51

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:53:26

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'None (None)'	Jennifer Leyva (b) (4) (b) (4)	14 Jan 2021 20:06:51

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:53:26

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'None (None)'	Jennifer Leyva (b) (4) (b) (4)	14 Jan 2021 20:06:51

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:53:26

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'None (None)'	Jennifer Leyva (b) (4) (b) (4)	14 Jan 2021 20:06:51

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:53:26

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered 'Day 2 (Day 2)'	Jennifer Leyva (b) (4)	14 Jan 2021 20:08:17

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:53:26

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered '12 Jan 2021'	Jennifer Leyva (b) (4)	14 Jan 2021 20:08:17

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:53:26

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered '0'	Jennifer Leyva (b) (4)	14 Jan 2021 20:08:17

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:53:26

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered missing code ND - Not Done.	Jennifer Leyva (b) (4) (b) (4)	14 Jan 2021 20:08:17

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:53:26

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User entered '%'	System	14 Jan 2021 20:08:17

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:53:26

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered missing code ND - Not Done.	Jennifer Leyva (b) (4) (b) (4)	14 Jan 2021 20:08:17

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:53:26

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'None (None)'	Jennifer Leyva (b) (4) (b) (4)	14 Jan 2021 20:08:17

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:53:26

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'Mild (Mild)'	Jennifer Leyva (b) (4) (b) (4)	14 Jan 2021 20:08:17

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:53:26

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'None (None)'	Jennifer Leyva (b) (4) (b) (4)	14 Jan 2021 20:08:17

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:53:26

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'None (None)'	Jennifer Leyva (b) (4) (b) (4)	14 Jan 2021 20:08:17

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:53:26

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'None (None)'	Jennifer Leyva (b) (4) (b) (4)	14 Jan 2021 20:08:17

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:53:26

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'None (None)'	Jennifer Leyva (b) (4) (b) (4)	14 Jan 2021 20:08:17

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:53:26

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'Moderate (Moderate)'	Jennifer Leyva (b) (4)	14 Jan 2021 20:08:17

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:53:26

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'Moderate (Moderate)'	Jennifer Leyva (b) (4) (b) (4)	14 Jan 2021 20:08:17

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:53:26

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'None (None)'	Jennifer Leyva (b) (4) (b) (4)	14 Jan 2021 20:08:17

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:53:26

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'None (None)'	Jennifer Leyva (b) (4) (b) (4)	14 Jan 2021 20:08:17

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:53:26

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'None (None)'	Jennifer Leyva (b) (4) (b) (4)	14 Jan 2021 20:08:17

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:53:26

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'None (None)'	Jennifer Leyva (b) (4) (b) (4)	14 Jan 2021 20:08:17

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:53:26

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'None (None)'	Jennifer Leyva (b) (4) (b) (4)	14 Jan 2021 20:08:17

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:53:26

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'None (None)'	Jennifer Leyva (b) (4) (b) (4)	14 Jan 2021 20:08:17

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:53:26

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'None (None)'	Jennifer Leyva (b) (4) (b) (4)	14 Jan 2021 20:08:17

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:53:26

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'None (None)'	Jennifer Leyva (b) (4) (b) (4)	14 Jan 2021 20:08:17

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:53:26

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered 'Day 3 (Day 3)'	Jennifer Leyva (b) (4)	14 Jan 2021 20:09:10

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:53:26

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered '13 Jan 2021'	Jennifer Leyva (b) (4) (b) (4)	14 Jan 2021 20:09:10

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:53:26

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered '0'	Jennifer Leyva (b) (4)	14 Jan 2021 20:09:10

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:53:26

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered missing code ND - Not Done.	Jennifer Leyva (b) (4) (b) (4)	14 Jan 2021 20:09:10

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:53:26

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User entered '%'	System	14 Jan 2021 20:09:10

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:53:26

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered missing code ND - Not Done.	Jennifer Leyva (b) (4) (b) (4)	14 Jan 2021 20:09:10

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:53:26

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
DataPoint Verified.		13 Apr 2021 17:02:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:45:59
DataPoint Verified.		11 Feb 2021 17:42:12
User entered 'None (None)'	Jennifer Leyva (b) (4) (b) (4)	14 Jan 2021 20:09:10

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:53:26

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'Mild (Mild)'	Jennifer Leyva (b) (4) (b) (4)	14 Jan 2021 20:09:10

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:53:26

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'None (None)'	Jennifer Leyva (b) (4)	14 Jan 2021 20:09:10

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:53:26

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'None (None)'	Jennifer Leyva (b) (4)	14 Jan 2021 20:09:10

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:53:26

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'None (None)'	Jennifer Leyva (b) (4)	14 Jan 2021 20:09:10

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:53:26

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'None (None)'	Jennifer Leyva (b) (4) (b) (4)	14 Jan 2021 20:09:10

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:53:26

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'None (None)'	Jennifer Leyva (b) (4)	14 Jan 2021 20:09:10

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:53:26

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'None (None)'	Jennifer Leyva (b) (4)	14 Jan 2021 20:09:10

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:53:26

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'None (None)'	Jennifer Leyva (b) (4)	14 Jan 2021 20:09:10

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:53:26

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'None (None)'	Jennifer Leyva (b) (4)	14 Jan 2021 20:09:10

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:53:26

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'None (None)'	Jennifer Leyva (b) (4)	14 Jan 2021 20:09:10

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:53:26

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'None (None)'	Jennifer Leyva (b) (4) (b) (4)	14 Jan 2021 20:09:10

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Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:53:26

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'None (None)'	Jennifer Leyva (b) (4)	14 Jan 2021 20:09:10

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Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:53:26

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'None (None)'	Jennifer Leyva (b) (4)	14 Jan 2021 20:09:10

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:53:26

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'None (None)'	Jennifer Leyva (b) (4)	14 Jan 2021 20:09:10

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:53:26

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'None (None)'	Jennifer Leyva (b) (4)	14 Jan 2021 20:09:10

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:53:26

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered 'Day 4 (Day 4)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 23:47:00

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:53:26

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered '14 Jan 2021'		19 Jan 2021 23:47:00

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:53:26

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered '0'		19 Jan 2021 23:47:00

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:53:26

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered '100'		19 Jan 2021 23:47:00

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:53:26

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User entered '%'	System	19 Jan 2021 23:47:00

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:53:26

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered '98.6' F		19 Jan 2021 23:47:00

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:53:26

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'None (None)'		19 Jan 2021 23:47:00

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:53:26

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'Mild (Mild)'		19 Jan 2021 23:47:00

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:53:26

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'None (None)'		19 Jan 2021 23:47:00

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:53:26

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'Mild (Mild)'		19 Jan 2021 23:47:00

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:53:26

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'Moderate (Moderate)'		19 Jan 2021 23:47:00

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:53:26

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'None (None)'		19 Jan 2021 23:47:00

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:53:26

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'Mild (Mild)'		19 Jan 2021 23:47:00

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:53:26

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User closed query 'Per source, subject had mild headache. Please review and reconcile. ' (Site from CRA).	(b) (4)	09 Mar 2021 19:42:44
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 19:42:41
Query 'Per source, subject had mild headache. Please review and reconcile. ' answered with 'updated' (Site from CRA).	Pamela Fidler (b) (4)	03 Mar 2021 19:06:59
User entered 'Mild (Mild)' reason for change: Data Entry Error	Pamela Fidler (b) (4)	03 Mar 2021 19:06:51
DataPoint Un-verified.	(b) (4), (b) (6)	11 Feb 2021 17:48:50
User opened query 'Per source, subject had mild headache. Please review and reconcile. ' (Site from CRA).		11 Feb 2021 17:48:49
DataPoint Verified.		11 Feb 2021 17:42:12
User entered 'None (None)'		19 Jan 2021 23:47:00

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:53:26

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'None (None)'		19 Jan 2021 23:47:00

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:53:26

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'None (None)'		19 Jan 2021 23:47:00

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:53:26

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'None (None)'		19 Jan 2021 23:47:00

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:53:26

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'None (None)'		19 Jan 2021 23:47:00

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:53:26

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'None (None)'		19 Jan 2021 23:47:00

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:53:26

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'None (None)'		19 Jan 2021 23:47:00

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:53:26

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'None (None)'		19 Jan 2021 23:47:00

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:53:26

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'Mild (Mild)'		19 Jan 2021 23:47:00

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:53:26

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered 'Day 5 (Day 5)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 23:48:32

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:53:26

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered '15 Jan 2021'		19 Jan 2021 23:48:32

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:53:26

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered '0'		19 Jan 2021 23:48:32

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:53:26

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered '99'		19 Jan 2021 23:48:32

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:53:26

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User entered '%'	System	19 Jan 2021 23:48:32

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:53:26

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered '101.2' F		19 Jan 2021 23:48:32

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:53:26

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'None (None)'		19 Jan 2021 23:48:32

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:53:26

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'None (None)'		19 Jan 2021 23:48:32

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:53:26

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'None (None)'		19 Jan 2021 23:48:32

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:53:26

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'None (None)'		19 Jan 2021 23:48:32

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:53:26

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'Moderate (Moderate)'		19 Jan 2021 23:48:32

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:53:26

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'Moderate (Moderate)'		19 Jan 2021 23:48:32

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:53:26

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'Moderate (Moderate)'		19 Jan 2021 23:48:32

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:53:26

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User closed query 'Per source, headache is documented as mild. Please review and reconcile. ' (Site from CRA).	(b) (4)	09 Mar 2021 19:42:54
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 19:42:52
Query 'Per source, headache is documented as mild. Please review and reconcile. ' answered with 'updated' (Site from CRA).	Pamela Fidler (b) (4)	03 Mar 2021 19:07:17
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	03 Mar 2021 19:07:10
DataPoint Un-verified.	(b) (4), (b) (6)	11 Feb 2021 17:50:02
User opened query 'Per source, headache is documented as mild. Please review and reconcile. ' (Site from CRA).	(b) (4), (b) (6)	11 Feb 2021 17:50:00
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	19 Jan 2021 23:48:32

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:53:26

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'None (None)'		19 Jan 2021 23:48:32

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:53:26

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'None (None)'		19 Jan 2021 23:48:32

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:53:26

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'None (None)'		19 Jan 2021 23:48:32

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:53:26

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'None (None)'		19 Jan 2021 23:48:32

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:53:26

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'None (None)'		19 Jan 2021 23:48:32

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:53:26

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'None (None)'		19 Jan 2021 23:48:32

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:53:26

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'None (None)'		19 Jan 2021 23:48:32

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:53:26

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'None (None)'		19 Jan 2021 23:48:32

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:53:26

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered 'Day 6 (Day 6)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 23:49:56

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:53:26

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered '16 Jan 2021'		19 Jan 2021 23:49:56

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:53:26

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered '0'		19 Jan 2021 23:49:56

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:53:26

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered '99'		19 Jan 2021 23:49:56

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:53:26

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User entered '%'	System	19 Jan 2021 23:49:56

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:53:26

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered '101' F		19 Jan 2021 23:49:56

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:53:26

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'None (None)'		19 Jan 2021 23:49:56

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:53:26

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'Mild (Mild)'		19 Jan 2021 23:49:56

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:53:26

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'None (None)'		19 Jan 2021 23:49:56

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:53:26

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'None (None)'		19 Jan 2021 23:49:56

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:53:26

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'Mild (Mild)'		19 Jan 2021 23:49:56

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:53:26

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'Mild (Mild)'		19 Jan 2021 23:49:56

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:53:26

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'Mild (Mild)'		19 Jan 2021 23:49:56

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:53:26

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'Moderate (Moderate)'		19 Jan 2021 23:49:56

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:53:26

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'None (None)'		19 Jan 2021 23:49:56

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:53:26

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'None (None)'		19 Jan 2021 23:49:56

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:53:26

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'Mild (Mild)'		19 Jan 2021 23:49:56

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:53:26

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'None (None)'		19 Jan 2021 23:49:56

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:53:26

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'Moderate (Moderate)'		19 Jan 2021 23:49:56

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:53:26

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'Moderate (Moderate)'		19 Jan 2021 23:49:56

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:53:26

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'Moderate (Moderate)'		19 Jan 2021 23:49:56

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:53:26

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'None (None)'		19 Jan 2021 23:49:56

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:53:26

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered 'Day 7 (Day 7)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 23:51:18

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:53:26

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered '17 Jan 2021'		19 Jan 2021 23:51:18

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:53:26

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered '0'		19 Jan 2021 23:51:18

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:53:26

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered '99'		19 Jan 2021 23:51:18

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:53:26

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User entered '%'	System	19 Jan 2021 23:51:18

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:53:26

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered '100' F		19 Jan 2021 23:51:18

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:53:26

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'None (None)'		19 Jan 2021 23:51:18

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:53:26

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'Mild (Mild)'		19 Jan 2021 23:51:18

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:53:26

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'None (None)'		19 Jan 2021 23:51:18

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:53:26

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'None (None)'		19 Jan 2021 23:51:18

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:53:26

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'Mild (Mild)'		19 Jan 2021 23:51:18

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:53:26

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'Mild (Mild)'		19 Jan 2021 23:51:18

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:53:26

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'Mild (Mild)'		19 Jan 2021 23:51:18

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:53:26

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'Mild (Mild)'		19 Jan 2021 23:51:18

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:53:26

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'None (None)'		19 Jan 2021 23:51:18

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:53:26

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'None (None)'		19 Jan 2021 23:51:18

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:53:26

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'Mild (Mild)'		19 Jan 2021 23:51:18

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:53:26

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'None (None)'		19 Jan 2021 23:51:18

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:53:26

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'Mild (Mild)'		19 Jan 2021 23:51:18

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:53:26

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'Moderate (Moderate)'		19 Jan 2021 23:51:18

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:53:26

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'Moderate (Moderate)'		19 Jan 2021 23:51:18

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:53:26

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'None (None)'		19 Jan 2021 23:51:18

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:53:26

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered 'Day 8 (Day 8)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 23:52:53

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:53:26

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered '18 Jan 2021'		19 Jan 2021 23:52:53

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:53:26

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered '0'		19 Jan 2021 23:52:53

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:53:26

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered '99'		19 Jan 2021 23:52:53

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:53:26

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User entered '%'	System	19 Jan 2021 23:52:53

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:53:26

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered '98.0' F		19 Jan 2021 23:52:53

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:53:26

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'None (None)'		19 Jan 2021 23:52:53

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:53:26

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'Mild (Mild)'		19 Jan 2021 23:52:53

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:53:26

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'None (None)'		19 Jan 2021 23:52:53

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:53:26

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'None (None)'		19 Jan 2021 23:52:53

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:53:26

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'Mild (Mild)'		19 Jan 2021 23:52:53

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:53:26

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'None (None)'		19 Jan 2021 23:52:53

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:53:26

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'None (None)'		19 Jan 2021 23:52:53

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:53:26

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'Mild (Mild)'		19 Jan 2021 23:52:53

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:53:26

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'Mild (Mild)'		19 Jan 2021 23:52:53

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:53:26

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'Mild (Mild)'		19 Jan 2021 23:52:53

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:53:26

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'Mild (Mild)'		19 Jan 2021 23:52:53

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:53:26

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'None (None)'		19 Jan 2021 23:52:53

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:53:26

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'Mild (Mild)'		19 Jan 2021 23:52:53

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:53:26

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'None (None)'		19 Jan 2021 23:52:53

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:53:26

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'Mild (Mild)'		19 Jan 2021 23:52:53

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:53:26

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'None (None)'		19 Jan 2021 23:52:53

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:53:26

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered 'Day 9 (Day 9)'	Jennifer Leyva (b) (4)	20 Jan 2021 00:20:31

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:53:26

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered '19 Jan 2021'	Jennifer Leyva (b) (4)	20 Jan 2021 00:20:31

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:53:26

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered '0'	Jennifer Leyva (b) (4)	20 Jan 2021 00:20:31

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:53:26

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered '87'	Jennifer Leyva (b) (4)	20 Jan 2021 00:20:31

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:53:26

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User entered '%'	System	20 Jan 2021 00:20:31

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:53:26

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered missing code ND - Not Done.	Jennifer Leyva (b) (4)	20 Jan 2021 00:20:31

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:53:26

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'None (None)'	Jennifer Leyva (b) (4)	20 Jan 2021 00:20:31

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:53:26

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'Mild (Mild)'	Jennifer Leyva (b) (4)	20 Jan 2021 00:20:31

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:53:26

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'Severe (Severe)'	Jennifer Leyva (b) (4)	20 Jan 2021 00:20:31

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:53:26

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'Severe (Severe)'	Jennifer Leyva (b) (4) (b) (4)	20 Jan 2021 00:20:31

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:53:26

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 13:56:12
User closed query 'Per source, subject reported mild fatigue. Please review and reconcile. ' (Site from CRA).		18 Mar 2021 13:56:09
Query 'Per source, subject reported mild fatigue. Please review and reconcile. ' answered with 'updated' (Site from CRA).	Pamela Fidler (b) (4)	03 Mar 2021 19:08:07
User entered 'Mild (Mild)' reason for change: Data Entry Error	Pamela Fidler (b) (4)	03 Mar 2021 19:07:59
DataPoint Un-verified.	(b) (4), (b) (6)	11 Feb 2021 18:03:10
User opened query 'Per source, subject reported mild fatigue. Please review and reconcile. ' (Site from CRA).		11 Feb 2021 18:02:23
DataPoint Verified.		11 Feb 2021 17:42:12
User entered 'None (None)'	Jennifer Leyva (b) (4) (b) (4)	20 Jan 2021 00:20:31

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:53:26

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 13:56:17
User closed query 'Per source, subject reported mild muscle aches. Please review and reconcile. ' (Site from CRA).		18 Mar 2021 13:56:15
Query 'Per source, subject reported mild muscle aches. Please review and reconcile. ' answered with 'updated' (Site from CRA).	Pamela Fidler (b) (4)	03 Mar 2021 19:08:14
User entered 'Mild (Mild)' reason for change: Data Entry Error	Pamela Fidler (b) (4)	03 Mar 2021 19:07:59
DataPoint Un-verified.	(b) (4), (b) (6)	11 Feb 2021 18:03:08
User opened query 'Per source, subject reported mild muscle aches. Please review and reconcile. ' (Site from CRA).		11 Feb 2021 18:02:36
DataPoint Verified.		11 Feb 2021 17:42:12
User entered 'None (None)'	Jennifer Leyva (b) (4) (b) (4)	20 Jan 2021 00:20:31

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:53:26

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 13:56:23
User closed query 'Per source, subject reported mild body aches. Please review and reconcile. ' (Site from CRA).		18 Mar 2021 13:56:21
Query 'Per source, subject reported mild body aches. Please review and reconcile. ' answered with 'updated' (Site from CRA).	Pamela Fidler (b) (4)	03 Mar 2021 19:08:20
User entered 'Mild (Mild)' reason for change: Data Entry Error	Pamela Fidler (b) (4)	03 Mar 2021 19:07:59
DataPoint Un-verified.	(b) (4), (b) (6)	11 Feb 2021 18:03:06
User opened query 'Per source, subject reported mild body aches. Please review and reconcile. ' (Site from CRA).		11 Feb 2021 18:02:48
DataPoint Verified.		11 Feb 2021 17:42:12
User entered 'None (None)'	Jennifer Leyva (b) (4) (b) (4)	20 Jan 2021 00:20:31

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:53:26

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 13:56:30
User closed query 'Per source, subject reported mild headache. Please review and reconcile. ' (Site from CRA).		18 Mar 2021 13:56:26
Query 'Per source, subject reported mild headache. Please review and reconcile. ' answered with 'updated' (Site from CRA).	Pamela Fidler (b) (4)	03 Mar 2021 19:08:27
User entered 'Mild (Mild)' reason for change: Data Entry Error	Pamela Fidler (b) (4)	03 Mar 2021 19:07:59
DataPoint Un-verified.	(b) (4), (b) (6)	11 Feb 2021 18:03:04
User opened query 'Per source, subject reported mild headache. Please review and reconcile. ' (Site from CRA).		11 Feb 2021 18:03:02
DataPoint Verified.		11 Feb 2021 17:42:12
User entered 'None (None)'	Jennifer Leyva (b) (4) (b) (4)	20 Jan 2021 00:20:31

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:53:26

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'Moderate (Moderate)'	Jennifer Leyva (b) (4)	20 Jan 2021 00:20:31

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:53:26

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'Moderate (Moderate)'	Jennifer Leyva (b) (4)	20 Jan 2021 00:20:31

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:53:26

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'None (None)'	Jennifer Leyva (b) (4)	20 Jan 2021 00:20:31

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:53:26

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'None (None)'	Jennifer Leyva (b) (4)	20 Jan 2021 00:20:31

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:53:26

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'None (None)'	Jennifer Leyva (b) (4)	20 Jan 2021 00:20:31

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:53:26

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'None (None)'	Jennifer Leyva (b) (4)	20 Jan 2021 00:20:31

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:53:26

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'None (None)'	Jennifer Leyva (b) (4)	20 Jan 2021 00:20:31

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:53:26

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'None (None)'	Jennifer Leyva (b) (4)	20 Jan 2021 00:20:31

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:53:26

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered 'Day 10 (Day 10)'	Jennifer Leyva (b) (4)	26 Jan 2021 21:15:01

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Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:53:26

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered '20 Jan 2021'	Jennifer Leyva (b) (4)	26 Jan 2021 21:15:01

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Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:53:26

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered '0'	Jennifer Leyva (b) (4)	26 Jan 2021 21:15:01

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Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:53:26

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered '94'	Jennifer Leyva (b) (4)	26 Jan 2021 21:15:01

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Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:53:26

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User entered '%'	System	26 Jan 2021 21:15:01

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:53:26

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered '97.0' F	Jennifer Leyva (b) (4) (b) (4)	26 Jan 2021 21:15:01

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:53:26

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'None (None)'	Jennifer Leyva (b) (4)	26 Jan 2021 21:15:01

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:53:26

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'Mild (Mild)'	Jennifer Leyva (b) (4)	26 Jan 2021 21:15:01

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:53:26

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'None (None)'	Jennifer Leyva (b) (4)	26 Jan 2021 21:15:01

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:53:26

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'None (None)'	Jennifer Leyva (b) (4) (b) (4)	26 Jan 2021 21:15:01

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:53:26

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'Mild (Mild)'	Jennifer Leyva (b) (4)	26 Jan 2021 21:15:01

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:53:26

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'None (None)'	Jennifer Leyva (b) (4) (b) (4)	26 Jan 2021 21:15:01

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:53:26

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'None (None)'	Jennifer Leyva (b) (4)	26 Jan 2021 21:15:01

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:53:26

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'None (None)'	Jennifer Leyva (b) (4) (b) (4)	26 Jan 2021 21:15:01

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:53:26

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'Mild (Mild)'	Jennifer Leyva (b) (4)	26 Jan 2021 21:15:01

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:53:26

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'Moderate (Moderate)'	Jennifer Leyva (b) (4)	26 Jan 2021 21:15:01

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:53:26

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'None (None)'	Jennifer Leyva (b) (4)	26 Jan 2021 21:15:01

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:53:26

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'None (None)'	Jennifer Leyva (b) (4)	26 Jan 2021 21:15:01

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:53:26

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'None (None)'	Jennifer Leyva (b) (4)	26 Jan 2021 21:15:01

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:53:26

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'None (None)'	Jennifer Leyva (b) (4)	26 Jan 2021 21:15:01

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:53:26

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'None (None)'	Jennifer Leyva (b) (4)	26 Jan 2021 21:15:01

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:53:26

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'None (None)'	Jennifer Leyva (b) (4)	26 Jan 2021 21:15:01

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:53:26

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered 'Day 11 (Day 11)'	Jennifer Leyva (b) (4)	26 Jan 2021 21:15:43

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:53:26

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered '21 Jan 2021'	Jennifer Leyva (b) (4)	26 Jan 2021 21:15:43

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:53:26

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered '0'	Jennifer Leyva (b) (4)	26 Jan 2021 21:15:43

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:53:26

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered '95'	Jennifer Leyva (b) (4)	26 Jan 2021 21:15:43

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:53:26

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User entered '%'	System	26 Jan 2021 21:15:43

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:53:26

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered '98.0' F	Jennifer Leyva (b) (4)	26 Jan 2021 21:15:43

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:53:26

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'None (None)'	Jennifer Leyva (b) (4)	26 Jan 2021 21:15:43

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:53:26

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'Mild (Mild)'	Jennifer Leyva (b) (4) (b) (4)	26 Jan 2021 21:15:43

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:53:26

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'None (None)'	Jennifer Leyva (b) (4) (b) (4)	26 Jan 2021 21:15:43

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:53:26

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'None (None)'	Jennifer Leyva (b) (4)	26 Jan 2021 21:15:43

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:53:26

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'Mild (Mild)'	Jennifer Leyva (b) (4)	26 Jan 2021 21:15:43

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:53:26

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'None (None)'	Jennifer Leyva (b) (4) (b) (4)	26 Jan 2021 21:15:43

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:53:26

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'None (None)'	Jennifer Leyva (b) (4)	26 Jan 2021 21:15:43

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:53:26

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'None (None)'	Jennifer Leyva (b) (4)	26 Jan 2021 21:15:43

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:53:26

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'None (None)'	Jennifer Leyva (b) (4)	26 Jan 2021 21:15:43

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:53:26

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'None (None)'	Jennifer Leyva (b) (4)	26 Jan 2021 21:15:43

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:53:26

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'None (None)'	Jennifer Leyva (b) (4)	26 Jan 2021 21:15:43

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:53:26

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'None (None)'	Jennifer Leyva (b) (4)	26 Jan 2021 21:15:43

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:53:26

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'None (None)'	Jennifer Leyva (b) (4)	26 Jan 2021 21:15:43

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:53:26

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'None (None)'	Jennifer Leyva (b) (4)	26 Jan 2021 21:15:43

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:53:26

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'None (None)'	Jennifer Leyva (b) (4)	26 Jan 2021 21:15:43

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:53:26

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'None (None)'	Jennifer Leyva (b) (4)	26 Jan 2021 21:15:43

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:53:26

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered 'Day 12 (Day 12)'	Jennifer Leyva (b) (4)	26 Jan 2021 21:16:15

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:53:26

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered '22 Jan 2021'	Jennifer Leyva (b) (4)	26 Jan 2021 21:16:15

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:53:26

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered '0'	Jennifer Leyva (b) (4)	26 Jan 2021 21:16:15

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:53:26

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered '93'	Jennifer Leyva (b) (4) (b) (4)	26 Jan 2021 21:16:15

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:53:26

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User entered '%'	System	26 Jan 2021 21:16:15

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:53:26

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered '98.0' F	Jennifer Leyva (b) (4)	26 Jan 2021 21:16:15

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:53:26

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'None (None)'	Jennifer Leyva (b) (4)	26 Jan 2021 21:16:15

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:53:26

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'Mild (Mild)'	Jennifer Leyva (b) (4) (b) (4)	26 Jan 2021 21:16:15

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:53:26

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'None (None)'	Jennifer Leyva (b) (4)	26 Jan 2021 21:16:15

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:53:26

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'None (None)'	Jennifer Leyva (b) (4)	26 Jan 2021 21:16:15

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:53:26

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'None (None)'	Jennifer Leyva (b) (4)	26 Jan 2021 21:16:15

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:53:26

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'None (None)'	Jennifer Leyva (b) (4)	26 Jan 2021 21:16:15

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:53:26

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'None (None)'	Jennifer Leyva (b) (4)	26 Jan 2021 21:16:15

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:53:26

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'Mild (Mild)'	Jennifer Leyva (b) (4)	26 Jan 2021 21:16:15

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:53:26

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'Mild (Mild)'	Jennifer Leyva (b) (4)	26 Jan 2021 21:16:15

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:53:26

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'Mild (Mild)'	Jennifer Leyva (b) (4)	26 Jan 2021 21:16:15

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:53:26

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'None (None)'	Jennifer Leyva (b) (4)	26 Jan 2021 21:16:15

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:53:26

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'None (None)'	Jennifer Leyva (b) (4)	26 Jan 2021 21:16:15

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:53:26

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'None (None)'	Jennifer Leyva (b) (4)	26 Jan 2021 21:16:15

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:53:26

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'None (None)'	Jennifer Leyva (b) (4)	26 Jan 2021 21:16:15

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:53:26

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'None (None)'	Jennifer Leyva (b) (4)	26 Jan 2021 21:16:15

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:53:26

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'None (None)'	Jennifer Leyva (b) (4)	26 Jan 2021 21:16:15

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:53:26

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered 'Day 13 (Day 13)'	Jennifer Leyva (b) (4)	01 Feb 2021 19:20:09

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:53:26

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered '23 Jan 2021'	Jennifer Leyva (b) (4)	01 Feb 2021 19:20:09

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:53:26

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'l'	Jennifer Leyva (b) (4)	01 Feb 2021 19:20:09

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:53:26

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered empty.	Jennifer Leyva (b) (4)	01 Feb 2021 19:20:09

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:53:26

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User entered empty.	System	01 Feb 2021 19:20:09

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:53:26

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	01 Feb 2021 19:20:09

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:53:26

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered empty.	Jennifer Leyva (b) (4)	01 Feb 2021 19:20:09

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:53:26

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered empty.	Jennifer Leyva (b) (4)	01 Feb 2021 19:20:09

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:53:26

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered empty.	Jennifer Leyva (b) (4)	01 Feb 2021 19:20:09

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:53:26

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered empty.	Jennifer Leyva (b) (4)	01 Feb 2021 19:20:09

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:53:26

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered empty.	Jennifer Leyva (b) (4)	01 Feb 2021 19:20:09

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:53:26

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered empty.	Jennifer Leyva (b) (4)	01 Feb 2021 19:20:09

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:53:26

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered empty.	Jennifer Leyva (b) (4)	01 Feb 2021 19:20:09

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:53:26

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered empty.	Jennifer Leyva (b) (4)	01 Feb 2021 19:20:09

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:53:26

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered empty.	Jennifer Leyva (b) (4)	01 Feb 2021 19:20:09

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:53:26

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered empty.	Jennifer Leyva (b) (4)	01 Feb 2021 19:20:09

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:53:26

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered empty.	Jennifer Leyva (b) (4)	01 Feb 2021 19:20:09

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:53:26

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered empty.	Jennifer Leyva (b) (4)	01 Feb 2021 19:20:09

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:53:26

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	01 Feb 2021 19:20:09

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:53:26

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered empty.	Jennifer Leyva (b) (4)	01 Feb 2021 19:20:09

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:53:26

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered empty.	Jennifer Leyva (b) (4)	01 Feb 2021 19:20:09

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:53:26

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	01 Feb 2021 19:20:09

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:53:26

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered 'Day 14 (Day 14)'	Jennifer Leyva (b) (4)	01 Feb 2021 19:20:18

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:53:26

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered '24 Jan 2021'	Jennifer Leyva (b) (4)	01 Feb 2021 19:20:18

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:53:26

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'l'	Jennifer Leyva (b) (4)	01 Feb 2021 19:20:18

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:53:26

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered empty.	Jennifer Leyva (b) (4)	01 Feb 2021 19:20:18

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:53:26

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User entered empty.	System	01 Feb 2021 19:20:18

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:53:26

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	01 Feb 2021 19:20:18

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:53:26

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	01 Feb 2021 19:20:18

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:53:26

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered empty.	Jennifer Leyva (b) (4)	01 Feb 2021 19:20:18

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:53:26

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered empty.	Jennifer Leyva (b) (4)	01 Feb 2021 19:20:18

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:53:26

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	01 Feb 2021 19:20:18

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:53:26

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered empty.	Jennifer Leyva (b) (4)	01 Feb 2021 19:20:18

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:53:26

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	01 Feb 2021 19:20:18

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:53:26

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered empty.	Jennifer Leyva (b) (4)	01 Feb 2021 19:20:18

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:53:26

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered empty.	Jennifer Leyva (b) (4)	01 Feb 2021 19:20:18

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:53:26

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered empty.	Jennifer Leyva (b) (4)	01 Feb 2021 19:20:18

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:53:26

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered empty.	Jennifer Leyva (b) (4)	01 Feb 2021 19:20:18

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:53:26

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered empty.	Jennifer Leyva (b) (4)	01 Feb 2021 19:20:18

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:53:26

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered empty.	Jennifer Leyva (b) (4)	01 Feb 2021 19:20:18

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:53:26

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered empty.	Jennifer Leyva (b) (4)	01 Feb 2021 19:20:18

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:53:26

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	01 Feb 2021 19:20:18

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:53:26

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered empty.	Jennifer Leyva (b) (4)	01 Feb 2021 19:20:18

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:53:26

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	01 Feb 2021 19:20:18

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:53:26

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered 'Day 15 (Day 15)'	Jennifer Leyva (b) (4)	01 Feb 2021 19:20:27

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:53:26

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered '25 Jan 2021'	Jennifer Leyva (b) (4)	01 Feb 2021 19:20:27

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:53:26

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'l'	Jennifer Leyva (b) (4)	01 Feb 2021 19:20:27

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:53:26

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered empty.	Jennifer Leyva (b) (4)	01 Feb 2021 19:20:27

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:53:26

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User entered empty.	System	01 Feb 2021 19:20:27

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:53:26

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered empty.	Jennifer Leyva (b) (4)	01 Feb 2021 19:20:27

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:53:26

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered empty.	Jennifer Leyva (b) (4)	01 Feb 2021 19:20:27

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:53:26

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered empty.	Jennifer Leyva (b) (4)	01 Feb 2021 19:20:27

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:53:26

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered empty.	Jennifer Leyva (b) (4)	01 Feb 2021 19:20:27

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:53:26

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered empty.	Jennifer Leyva (b) (4)	01 Feb 2021 19:20:27

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:53:26

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered empty.	Jennifer Leyva (b) (4)	01 Feb 2021 19:20:27

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:53:26

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	01 Feb 2021 19:20:27

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:53:26

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered empty.	Jennifer Leyva (b) (4)	01 Feb 2021 19:20:27

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:53:26

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered empty.	Jennifer Leyva (b) (4)	01 Feb 2021 19:20:27

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:53:26

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	01 Feb 2021 19:20:27

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:53:26

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered empty.	Jennifer Leyva (b) (4)	01 Feb 2021 19:20:27

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:53:26

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered empty.	Jennifer Leyva (b) (4)	01 Feb 2021 19:20:27

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:53:26

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered empty.	Jennifer Leyva (b) (4)	01 Feb 2021 19:20:27

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:53:26

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered empty.	Jennifer Leyva (b) (4)	01 Feb 2021 19:20:27

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:53:26

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered empty.	Jennifer Leyva (b) (4)	01 Feb 2021 19:20:27

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:53:26

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered empty.	Jennifer Leyva (b) (4)	01 Feb 2021 19:20:27

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:53:26

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered empty.	Jennifer Leyva (b) (4)	01 Feb 2021 19:20:27

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:53:26

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered 'Day 16 (Day 16)'	Jennifer Leyva (b) (4)	01 Feb 2021 19:20:39

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:53:26

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User closed query 'Per ETRTR: Per protocol, please add log line for 27Jan21 and fill with Symptoms reported by subject or indicate Assessments Not done according to the case, thanks.' (Site from CRA).	(b) (4), (b) (6)	11 Feb 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
Query 'Per ETRTR: Per protocol, please add log line for 27Jan21 and fill with Symptoms reported by subject or indicate Assessments Not done according to the case, thanks.' answered with 'Subject was called x3 but did not answer or return call.' (Site from CRA).	Jennifer Leyva (b) (4)	10 Feb 2021 21:37:36
User opened query 'Per ETRTR: Per protocol, please add log line for 27Jan21 and fill with Symptoms reported by subject or indicate Assessments Not done according to the case, thanks.' (Site from CRA).	(b) (4), (b) (6)	09 Feb 2021 20:24:59
User entered '26 Jan 2021'	Jennifer Leyva (b) (4)	01 Feb 2021 19:20:39

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:53:26

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered 'l'	Jennifer Leyva (b) (4)	01 Feb 2021 19:20:39

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:53:26

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered empty.	Jennifer Leyva (b) (4)	01 Feb 2021 19:20:39

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:53:26

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User entered empty.	System	01 Feb 2021 19:20:39

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:53:26

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	01 Feb 2021 19:20:39

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:53:26

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered empty.	Jennifer Leyva (b) (4)	01 Feb 2021 19:20:39

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:53:26

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered empty.	Jennifer Leyva (b) (4)	01 Feb 2021 19:20:39

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:53:26

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered empty.	Jennifer Leyva (b) (4)	01 Feb 2021 19:20:39

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:53:26

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered empty.	Jennifer Leyva (b) (4)	01 Feb 2021 19:20:39

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:53:26

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered empty.	Jennifer Leyva (b) (4)	01 Feb 2021 19:20:39

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:53:26

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	01 Feb 2021 19:20:39

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:53:26

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered empty.	Jennifer Leyva (b) (4)	01 Feb 2021 19:20:39

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:53:26

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered empty.	Jennifer Leyva (b) (4)	01 Feb 2021 19:20:39

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:53:26

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered empty.	Jennifer Leyva (b) (4)	01 Feb 2021 19:20:39

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:53:26

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered empty.	Jennifer Leyva (b) (4)	01 Feb 2021 19:20:39

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:53:26

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered empty.	Jennifer Leyva (b) (4)	01 Feb 2021 19:20:39

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:53:26

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered empty.	Jennifer Leyva (b) (4)	01 Feb 2021 19:20:39

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:53:26

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered empty.	Jennifer Leyva (b) (4)	01 Feb 2021 19:20:39

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:53:26

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered empty.	Jennifer Leyva (b) (4)	01 Feb 2021 19:20:39

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:53:26

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered empty.	Jennifer Leyva (b) (4)	01 Feb 2021 19:20:39

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:53:26

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:08:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:42:12
User entered empty.	Jennifer Leyva (b) (4)	01 Feb 2021 19:20:39

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 21:53:26

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:09:02
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:11:47
User entered '13 Jan 2021'	Jennifer Leyva (b) (4) (b) (4)	14 Jan 2021 20:09:38

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 21:53:26

[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 21:09:02
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 18:11:47
User entered 'Yes (Y)'	Jennifer Leyva (b) (4)	14 Jan 2021 20:09:38

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 21:53:26

[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 21:09:02
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:11:47
User closed query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	(b) (4)	21 Jan 2021 08:28:04
User closed query 'Data is required. Please complete.' (Site from System).		21 Jan 2021 08:27:38
Query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' answered with 'Previously completed.' (Site from System).	Jennifer Leyva (b) (4) (b) (4)	20 Jan 2021 16:41:07
User opened query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	System	20 Jan 2021 16:40:54
User entered 'Yes (Y)' reason for change: New Information	Jennifer Leyva (b) (4) (b) (4)	20 Jan 2021 16:40:54
Query 'Data is required. Please complete.' answered with 'To be updated once results are received' (Site from System).	Jennifer Leyva (b) (4) (b) (4)	14 Jan 2021 20:09:48
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Jan 2021 20:09:38
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	14 Jan 2021 20:09:38

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Folder: Covid-19 Assessment 12 Jan 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 21:53:26

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:09:02
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:11:47
User entered '13 Jan 2021'	Jennifer Leyva (b) (4) (b) (4)	14 Jan 2021 20:09:38

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Folder: Covid-19 Assessment 12 Jan 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 21:53:26

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:09:02
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 18:11:47
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Jennifer Leyva (b) (4)	14 Jan 2021 20:09:38

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 21:53:26

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:09:02
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 18:11:47
User entered empty.	Jennifer Leyva (b) (4)	14 Jan 2021 20:09:38

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Folder: Covid-19 Assessment 12 Jan 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 21:53:26

[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 21:09:02
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 18:11:47
User entered 'No (N)'	Jennifer Leyva (b) (4)	14 Jan 2021 20:09:38

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 21:53:26

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:09:02
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 18:11:47
User entered empty.	Jennifer Leyva (b) (4)	14 Jan 2021 20:09:38

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Folder: Covid-19 Assessment 12 Jan 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 21:53:26

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:09:02
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 18:11:47
User entered empty.	Jennifer Leyva (b) (4)	14 Jan 2021 20:09:38

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Folder: Covid-19 Assessment 12 Jan 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 21:53:26

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:09:02
User entered 'I'	System	20 Jan 2021 16:40:54

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:53:26

[Did the subject have Respiratory Rates \$\geq\$ 30 per Minute?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:09:08
DataPoint Verified.		13 Apr 2021 17:17:17
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered 'No (N)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	20 Jan 2021 16:41:32

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Folder: Covid-19 Assessment 12 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:53:26

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:09:08
DataPoint Verified.		13 Apr 2021 17:17:17
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered empty.	(b) (4) Jennifer Leyva (b) (4) (b) (4)	20 Jan 2021 16:41:32

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:53:26

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:09:08
DataPoint Verified.		13 Apr 2021 17:17:17
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered empty.	(b) (4) Jennifer Leyva (b) (4) (b) (4)	20 Jan 2021 16:41:32

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:53:26

[Respiratory Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:09:08
DataPoint Verified.		13 Apr 2021 17:17:17
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered empty.	(b) (4) Jennifer Leyva (b) (4) (b) (4)	20 Jan 2021 16:41:32

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Folder: Covid-19 Assessment 12 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:53:26

[Did the subject have Heart Rate \$\geq\$ 125 beats per minute](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:09:08
DataPoint Verified.		13 Apr 2021 17:17:17
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered 'No (N)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	20 Jan 2021 16:41:32

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:53:26

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:09:08
DataPoint Verified.		13 Apr 2021 17:17:17
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered empty.	(b) (4) Jennifer Leyva (b) (4) (b) (4)	20 Jan 2021 16:41:32

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:53:26

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:09:08
DataPoint Verified.		13 Apr 2021 17:17:17
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered empty.	(b) (4) Jennifer Leyva (b) (4) (b) (4)	20 Jan 2021 16:41:32

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Folder: Covid-19 Assessment 12 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:53:26

[Heart Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:09:08
DataPoint Verified.		13 Apr 2021 17:17:17
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered empty.	(b) (4) Jennifer Leyva (b) (4) (b) (4)	20 Jan 2021 16:41:32

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Folder: Covid-19 Assessment 12 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:53:26

Did the subject have Oxygen Saturation of SpO2 \leq 93% on room air at sea level?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:09:08
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:16:34
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User closed query 'Per source, subject SpO2 is documented as 87% on 19-Jan-2021. Please review and reconcile. ' (Site from CRA).	(b) (4) (b) (4), (b) (6)	09 Mar 2021 19:42:20
Query 'Per source, subject SpO2 is documented as 87% on 19-Jan-2021. Please review and reconcile. ' answered with 'updated' (Site from CRA).	Pamela Fidler (b) (4)	03 Mar 2021 19:04:35
User entered 'Yes (Y)' reason for change: Data Entry Error	Pamela Fidler (b) (4)	03 Mar 2021 19:04:26
User opened query 'Per source, subject SpO2 is documented as 87% on 19-Jan-2021. Please review and reconcile. ' (Site from CRA).	(b) (4), (b) (6)	11 Feb 2021 18:12:55
User entered 'No (N)'	Jennifer Leyva (b) (4)	20 Jan 2021 16:41:32

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:53:26

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:09:08
DataPoint Verified.		13 Apr 2021 17:16:41
DataPoint Un-verified.		13 Apr 2021 17:16:39
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 19:11:27
User closed query 'Please clarify date as 19Jan2021 or 12Jan2021' (Site from CRA).		25 Mar 2021 19:11:12
Query 'Please clarify date as 19Jan2021 or 12Jan2021' answered with '19JAN2021 was the date when she had the lowest o2 ' (Site from CRA).	Pamela Fidler (b) (4)	25 Mar 2021 17:14:53
User entered '19 Jan 2021' reason for change: Data Entry Error	Pamela Fidler (b) (4)	25 Mar 2021 17:14:42
User opened query 'Please clarify date as 19Jan2021 or 12Jan2021' (Site from CRA).	(b) (4), (b) (6)	23 Mar 2021 22:43:41
User closed query 'Per Source SpO2 is documented as 87% on 19-Jan-2021. Please enter data for the this section of eCRF. ' (Site from CRA).		23 Mar 2021 22:43:41
Query 'Per Source SpO2 is documented as 87% on 19-Jan-2021. Please enter data for the this section of eCRF. ' answered with 'updated' (Site from CRA).	Pamela Fidler (b) (4)	09 Mar 2021 20:58:47
User entered '12 Jan 2021' reason for change: Data Entry Error	Pamela Fidler (b) (4)	09 Mar 2021 20:58:40
User opened query 'Per Source SpO2 is documented as 87% on 19-Jan-2021. Please enter data for the this section of eCRF. ' (Site from CRA).	(b) (4), (b) (6)	09 Mar 2021 19:42:01
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	20 Jan 2021 16:41:32

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Folder: Covid-19 Assessment 12 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:53:26

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:09:08
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:49:44
User signature succeeded.	Laurence Chu (b) (4)	22 Apr 2021 23:56:31
User closed query 'Per CDM : Please note as per the Symptom log the O2 saturation is 93% on Day 12 (22Jan2021), Kindly check the end date in severity form as it does not reconcile with the symptom log and make appropriate corrections or else clarify. Thanks ' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:44:30
Query 'Per CDM : Please note as per the Symptom log the O2 saturation is 93% on Day 12 (22Jan2021), Kindly check the end date in severity form as it does not reconcile with the symptom log and make appropriate corrections or else clarify. Thanks ' answered with 'Corrected' (Site from DM).	Jennifer Leyva (b) (4) (b) (4)	21 Apr 2021 13:21:41
DataPoint Un-verified.	Jennifer Leyva (b) (4) (b) (4)	21 Apr 2021 13:18:24
Signature has been broken.	Jennifer Leyva (b) (4) (b) (4)	21 Apr 2021 13:18:24
User entered '22 Jan 2021' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	21 Apr 2021 13:18:24
User opened query 'Per CDM : Please note as per the Symptom log the O2 saturation is 93% on Day 12 (22Jan2021), Kindly check the end date in severity form as it does not reconcile with the symptom log and make appropriate corrections or else clarify. Thanks ' (Site from DM).	(b) (4), (b) (6)	21 Apr 2021 11:18:02
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	15 Apr 2021 16:38:30
User closed query 'Per CDM: Did the subject have Oxygen Saturation of SpO2 ≤ 93% on room air at sea level? Is marked YES, however “end date” is missing Please review and reconcile. Else clarify' (Site from DM).	(b) (4), (b) (6)	14 Apr 2021 20:27:19
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:16:49

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Folder: Covid-19 Assessment 12 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:53:26

[End Date](#)

Audit	User	Time (GMT)
Query 'Per CDM: Did the subject have Oxygen Saturation of SpO2 <u><</u> 93% on room air at sea level? Is marked YES, however “end date” is missing. Please review and reconcile. Else clarify' answered with 'Updated' (Site from DM). Signature has been broken.	Pamela Fidler (b) (4) (b) (4) (b) (4)	09 Apr 2021 15:22:57
	Pamela Fidler (b) (4) (b) (4) (b) (4)	09 Apr 2021 15:22:37
User entered '20 Jan 2021' reason for change: Data Entry Error	Pamela Fidler (b) (4) (b) (4) (b) (4)	09 Apr 2021 15:22:37
User opened query 'Per CDM: Did the subject have Oxygen Saturation of SpO2 ≤ 93% on room air at sea level? Is marked YES, however “end date” is missing. Please review and reconcile. Else clarify' (Site from DM).	(b) (4), (b) (6) (b) (4)	09 Apr 2021 05:12:35
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:15:03
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	20 Jan 2021 16:41:32

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Folder: Covid-19 Assessment 12 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:53:26

[Oxygen Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:09:08
DataPoint Verified.		13 Apr 2021 17:16:47
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered '87' reason for change: Data Entry Error	(b) (4) Pamela Fidler (b) (4)	09 Mar 2021 20:58:40
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	20 Jan 2021 16:41:32

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Folder: Covid-19 Assessment 12 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:53:26

[Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:09:08
DataPoint Verified.		13 Apr 2021 17:17:17
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered 'No (N)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	20 Jan 2021 16:41:32

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Folder: Covid-19 Assessment 12 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:53:26

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:09:08
DataPoint Verified.		13 Apr 2021 17:17:17
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered empty.	(b) (4) Jennifer Leyva (b) (4) (b) (4)	20 Jan 2021 16:41:32

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Folder: Covid-19 Assessment 12 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:53:26

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:09:08
DataPoint Verified.		13 Apr 2021 17:17:17
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered empty.	(b) (4) Jennifer Leyva (b) (4) (b) (4)	20 Jan 2021 16:41:32

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Folder: Covid-19 Assessment 12 Jan 2021

Form: Covid-19 Severity Assessment

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[PaO2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:09:08
DataPoint Verified.		13 Apr 2021 17:17:17
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered empty.	(b) (4) Jennifer Leyva (b) (4) (b) (4)	20 Jan 2021 16:41:32

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Folder: Covid-19 Assessment 12 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:53:26

[Did the subject have Respiratory failure?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:09:08
DataPoint Verified.		13 Apr 2021 17:17:17
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered 'No (N)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	20 Jan 2021 16:41:32

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Folder: Covid-19 Assessment 12 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:53:26

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:09:08
DataPoint Verified.		13 Apr 2021 17:17:17
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered empty.	(b) (4) Jennifer Leyva (b) (4) (b) (4)	20 Jan 2021 16:41:32

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Folder: Covid-19 Assessment 12 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:53:26

Did the subject have Acute Respiratory Distress Syndrome (ARDS)?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:09:08
DataPoint Verified.		13 Apr 2021 17:17:17
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
	System	20 Jan 2021 16:49:41
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Jan 2021 16:49:41
User entered 'No (N)' reason for change: Data Entry Error	Jennifer Leyva (b) (4)	20 Jan 2021 16:49:41
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Jan 2021 16:41:32
User entered empty.	Jennifer Leyva (b) (4)	20 Jan 2021 16:41:32
	(b) (4)	

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Generated On: 11 Aug 2021 21:53:26

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:09:08
DataPoint Verified.		13 Apr 2021 17:17:17
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered empty.	(b) (4) Jennifer Leyva (b) (4) (b) (4)	20 Jan 2021 16:41:32

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Folder: Covid-19 Assessment 12 Jan 2021

Form: Covid-19 Severity Assessment

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[High-Flow Oxygen?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:09:08
DataPoint Verified.		13 Apr 2021 17:17:17
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered empty.	(b) (4) Jennifer Leyva (b) (4) (b) (4)	20 Jan 2021 16:41:32

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Folder: Covid-19 Assessment 12 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:53:26

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:09:08
DataPoint Verified.		13 Apr 2021 17:17:17
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered empty.	(b) (4) Jennifer Leyva (b) (4) (b) (4)	20 Jan 2021 16:41:32

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Folder: Covid-19 Assessment 12 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:53:26

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:09:08
DataPoint Verified.		13 Apr 2021 17:17:17
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered empty.	(b) (4) Jennifer Leyva (b) (4) (b) (4)	20 Jan 2021 16:41:32

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Folder: Covid-19 Assessment 12 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:53:26

[Non-Invasive Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:09:08
DataPoint Verified.		13 Apr 2021 17:17:17
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered empty.	(b) (4) Jennifer Leyva (b) (4) (b) (4)	20 Jan 2021 16:41:32

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Folder: Covid-19 Assessment 12 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:53:26

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:09:08
DataPoint Verified.		13 Apr 2021 17:17:17
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered empty.	(b) (4) Jennifer Leyva (b) (4) (b) (4)	20 Jan 2021 16:41:32

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Folder: Covid-19 Assessment 12 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:53:26

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:09:08
DataPoint Verified.		13 Apr 2021 17:17:17
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered empty.	(b) (4) Jennifer Leyva (b) (4) (b) (4)	20 Jan 2021 16:41:32

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Folder: Covid-19 Assessment 12 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:53:26

[Mechanical Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:09:08
DataPoint Verified.		13 Apr 2021 17:17:17
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered empty.	(b) (4) Jennifer Leyva (b) (4) (b) (4)	20 Jan 2021 16:41:32

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:53:26

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:09:08
DataPoint Verified.		13 Apr 2021 17:17:17
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered empty.	(b) (4) Jennifer Leyva (b) (4) (b) (4)	20 Jan 2021 16:41:32

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:53:26

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:09:08
DataPoint Verified.		13 Apr 2021 17:17:17
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered empty.	(b) (4) Jennifer Leyva (b) (4) (b) (4)	20 Jan 2021 16:41:32

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Folder: Covid-19 Assessment 12 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:53:26

[ECMO?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:09:08
DataPoint Verified.		13 Apr 2021 17:17:17
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered empty.	(b) (4) Jennifer Leyva (b) (4) (b) (4)	20 Jan 2021 16:41:32

US3012329

Folder: Covid-19 Assessment 12 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:53:26

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:09:08
DataPoint Verified.		13 Apr 2021 17:17:17
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered empty.	(b) (4) Jennifer Leyva (b) (4) (b) (4)	20 Jan 2021 16:41:32

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Folder: Covid-19 Assessment 12 Jan 2021

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Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:09:08
DataPoint Verified.		13 Apr 2021 17:17:17
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered empty.	(b) (4) Jennifer Leyva (b) (4) (b) (4)	20 Jan 2021 16:41:32

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Folder: Covid-19 Assessment 12 Jan 2021

Form: Covid-19 Severity Assessment

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[Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:09:08
DataPoint Verified.		13 Apr 2021 17:17:17
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered 'No (N)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	20 Jan 2021 16:41:32

US3012329

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:09:08
DataPoint Verified.		13 Apr 2021 17:17:17
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered empty.	(b) (4) Jennifer Leyva (b) (4) (b) (4)	20 Jan 2021 16:41:32

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:09:08
DataPoint Verified.		13 Apr 2021 17:17:17
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered empty.	(b) (4) Jennifer Leyva (b) (4) (b) (4)	20 Jan 2021 16:41:32

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Folder: Covid-19 Assessment 12 Jan 2021

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[Evidence of Shock Requires
Vasopressors](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:09:08
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:17:17
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered 'No (N)'	Jennifer Leyva (b) (4)	20 Jan 2021 16:41:32

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:09:08
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:17:17
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered empty.	Jennifer Leyva (b) (4)	20 Jan 2021 16:41:32

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:09:08
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:17:17
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered empty.	Jennifer Leyva (b) (4)	20 Jan 2021 16:41:32

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Folder: Covid-19 Assessment 12 Jan 2021

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[Acute Renal Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:09:08
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:17:17
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered 'No (N)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	20 Jan 2021 16:41:32

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Folder: Covid-19 Assessment 12 Jan 2021

Form: Covid-19 Severity Assessment

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:09:08
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:17:17
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered empty.	(b) (4) Jennifer Leyva (b) (4) (b) (4)	20 Jan 2021 16:41:32

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Folder: Covid-19 Assessment 12 Jan 2021

Form: Covid-19 Severity Assessment

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[Hepatic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:09:08
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:17:17
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered 'No (N)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	20 Jan 2021 16:41:32

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Folder: Covid-19 Assessment 12 Jan 2021

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:09:08
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:17:17
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered empty.	(b) (4) Jennifer Leyva (b) (4) (b) (4)	20 Jan 2021 16:41:32

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Folder: Covid-19 Assessment 12 Jan 2021

Form: Covid-19 Severity Assessment

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[Neurologic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:09:08
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:17:17
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered 'No (N)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	20 Jan 2021 16:41:32

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:09:08
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:17:17
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered empty.	Jennifer Leyva (b) (4)	20 Jan 2021 16:41:32

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[Clinical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:09:08
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:17:17
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered 'No (N)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	20 Jan 2021 16:41:32

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[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:09:08
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:17:17
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered empty.	Jennifer Leyva (b) (4)	20 Jan 2021 16:41:32

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Folder: Covid-19 Assessment 12 Jan 2021

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[Radiographical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:09:08
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:17:17
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered 'No (N)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	20 Jan 2021 16:41:32

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Folder: Covid-19 Assessment 12 Jan 2021

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[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:09:08
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:17:17
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered empty.	Jennifer Leyva (b) (4)	20 Jan 2021 16:41:32

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Folder: Covid-19 Assessment 12 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:53:26

[Admission to an intensive care unit due to SARS-CoV-2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:09:08
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:17:17
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered 'No (N)'	Jennifer Leyva (b) (4)	20 Jan 2021 16:41:32

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Folder: Covid-19 Assessment 12 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:53:26

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:09:08
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:17:17
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered empty.	Jennifer Leyva (b) (4)	20 Jan 2021 16:41:32

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Folder: Covid-19 Assessment 12 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:53:26

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:09:08
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:17:17
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered empty.	Jennifer Leyva (b) (4)	20 Jan 2021 16:41:32

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Folder: Covid-19 Assessment 12 Jan 2021

Form: Generate Next COVID-19 Assessment

Generated On: 11 Aug 2021 21:53:26

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:09:14
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:33:10
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered 'No (N)'	Jennifer Leyva (b) (4)	14 Jan 2021 20:09:54

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Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 21:53:26

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:05:34
User accepted default value 'Day 3 (Day 3)'	Jennifer Leyva (b) (4) (b) (4)	10 Feb 2021 21:36:26

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Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 21:53:26

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:05:34
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:23:06
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered 'Yes (Y)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	10 Feb 2021 21:36:26

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Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 21:53:26

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:05:34
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:23:06
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered '15 Jan 2021'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	10 Feb 2021 21:36:26

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Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 21:53:26

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:05:34
User accepted default value 'Day 5 (Day 5)'	Jennifer Leyva (b) (4) (b) (4)	10 Feb 2021 21:36:26

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Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 21:53:26

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:05:34
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:22:59
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered 'Yes (Y)'	Jennifer Leyva (b) (4)	10 Feb 2021 21:36:26

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Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 21:53:26

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:05:34
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:22:59
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered '17 Jan 2021'	Jennifer Leyva (b) (4)	10 Feb 2021 21:36:26

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Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 21:53:26

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:05:34
User accepted default value 'Day 7 (Day 7)'	Jennifer Leyva (b) (4) (b) (4)	10 Feb 2021 21:36:26

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Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 21:53:26

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:05:34
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:22:54
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered 'Yes (Y)'	Jennifer Leyva (b) (4)	10 Feb 2021 21:36:26

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Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 21:53:26

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:05:34
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:22:54
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered '19 Jan 2021'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	10 Feb 2021 21:36:26

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Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 21:53:26

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:05:34
User accepted default value 'Day 9 (Day 9)'	Jennifer Leyva (b) (4) (b) (4)	10 Feb 2021 21:36:26

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Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 21:53:26

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:05:34
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:22:50
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered 'Yes (Y)'	Jennifer Leyva (b) (4)	10 Feb 2021 21:36:26

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Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 21:53:26

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:05:34
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:22:50
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered '21 Jan 2021'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	10 Feb 2021 21:36:26

US3012329

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 21:53:26

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:05:34
User closed query 'Per GCL LAB reconciliation: Saliva: PPD reports Day 14 sample with Accession # 1F652491990 is reported with 26JAN2021 date of Collection and which is missing in EDC. Please review the Accession # in Preclarus and confirm the correct date and sample label then record on the Saliva collection form. Thank you.' (Site from DM).		04 Mar 2021 11:29:00
Query 'Per GCL LAB reconciliation: Saliva: PPD reports Day 14 sample with Accession # 1F652491990 is reported with 26JAN2021 date of Collection and which is missing in EDC. Please review the Accession # in Preclarus and confirm the correct date and sample label then record on the Saliva collection form. Thank you.' answered with 'corrected edc' (Site from DM).	Pamela Fidler (b) (4)	03 Mar 2021 19:09:32
User opened query 'Per GCL LAB reconciliation: Saliva: PPD reports Day 14 sample with Accession # 1F652491990 is reported with 26JAN2021 date of Collection and which is missing in EDC. Please review the Accession # in Preclarus and confirm the correct date and sample label then record on the Saliva collection form. Thank you.' (Site from DM).	(b) (4), (b) (6)	12 Feb 2021 13:21:16
User accepted default value 'Day 14 (Day 14)'	Jennifer Leyva (b) (4)	10 Feb 2021 21:36:26

US3012329

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 21:53:26

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:05:34
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:26:55
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered 'Yes (Y)'	Jennifer Leyva (b) (4)	10 Feb 2021 21:36:26

US3012329

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 21:53:26

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:05:34
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:26:55
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered '26 Jan 2021' reason for change: Data Entry Error	(b) (4) Pamela Fidler (b) (4)	03 Mar 2021 19:09:17
User entered '25 Jan 2021'	Jennifer Leyva (b) (4)	10 Feb 2021 21:36:26

US3012329

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 21:53:26

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:05:34
User closed query 'Per GCL LAB reconciliation: Saliva: PPD reports Day 21 sample with Accession # 1F657206294 is reported with 02FEB2021 date of Collection and which is missing in EDC. Please review the Accession # in Preclarus and confirm the correct date and sample label then record on the Saliva collection form. Thank you' (Site from DM).		04 Mar 2021 11:29:14
Query 'Per GCL LAB reconciliation: Saliva: PPD reports Day 21 sample with Accession # 1F657206294 is reported with 02FEB2021 date of Collection and which is missing in EDC. Please review the Accession # in Preclarus and confirm the correct date and sample label then record on the Saliva collection form. Thank you' answered with 'corrected edc' (Site from DM).	Pamela Fidler (b) (4)	03 Mar 2021 19:09:52
User opened query 'Per GCL LAB reconciliation: Saliva: PPD reports Day 21 sample with Accession # 1F657206294 is reported with 02FEB2021 date of Collection and which is missing in EDC. Please review the Accession # in Preclarus and confirm the correct date and sample label then record on the Saliva collection form. Thank you' (Site from DM).	(b) (4), (b) (6)	12 Feb 2021 13:22:12
User accepted default value 'Day 21 (Day 21)'	Jennifer Leyva (b) (4)	10 Feb 2021 21:36:26

US3012329

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 21:53:26

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:05:34
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:26:55
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered 'Yes (Y)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	10 Feb 2021 21:36:26

US3012329

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 21:53:26

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:05:34
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:26:55
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered '02 Feb 2021' reason for change: Data Entry Error	(b) (4)	
	Pamela Fidler (b) (4)	03 Mar 2021 19:09:44
User entered '01 Feb 2021'	Jennifer Leyva (b) (4)	10 Feb 2021 21:36:26
	(b) (4)	

US3012329

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 21:53:26

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:05:34
User closed query 'Per GCL Lab Reconciliation: Saliva : For Day 28, EDC Sample Collected is No, however in PPD Central Lab sample dated 22feb2021 (Accession # 1F638125804) is reported. Hence please confirm correct date of collection for Day 28 and update EDC or PPD Central lab.' (Site from DM).		11 Mar 2021 07:24:37
Query 'Per GCL Lab Reconciliation: Saliva : For Day 28, EDC Sample Collected is No, however in PPD Central Lab sample dated 22feb2021 (Accession # 1F638125804) is reported. Hence please confirm correct date of collection for Day 28 and update EDC or PPD Central lab.' answered with 'Will update ppd ' (Site from DM).	Pamela Fidler (b) (4)	08 Mar 2021 21:29:30
User opened query 'Per GCL Lab Reconciliation: Saliva : For Day 28, EDC Sample Collected is No, however in PPD Central Lab sample dated 22feb2021 (Accession # 1F638125804) is reported. Hence please confirm correct date of collection for Day 28 and update EDC or PPD Central lab.' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 06:22:53
User accepted default value 'Day 28 (Day 28)'	Jennifer Leyva (b) (4) (b) (4)	10 Feb 2021 21:36:26

US3012329

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 21:53:26

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:05:34
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:19:25
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 15:00:49
User closed query 'Per GCL Lab Reconciliation: Saliva: Re-query: Sample dated 22FEB2021 with Accession number 1F638125804 is reported under Illness Visit Day 28 in Preclarus portal, please review and update in EDC , to reflect correct with PPD central lab, if no sample collected on this day then please review the preclaus data and update the sample details to correct subject ID and visit in PPD portal, confirm the subject ID and visit in query response, thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	31 Mar 2021 13:18:12
Query 'Per GCL Lab Reconciliation: Saliva: Re-query: Sample dated 22FEB2021 with Accession number 1F638125804 is reported under Illness Visit Day 28 in Preclarus portal, please review and update in EDC , to reflect correct with PPD central lab, if no sample collected on this day then please review the preclaus data and update the sample details to correct subject ID and visit in PPD portal, confirm the subject ID and visit in query response, thank you.' answered with 'Updated' (Site from DM).	Pamela Fidler (b) (4)	30 Mar 2021 15:03:59
Signature has been broken.	Pamela Fidler (b) (4)	30 Mar 2021 15:03:37
User entered 'Yes (Y)' reason for change: Data Entry Error	Pamela Fidler (b) (4)	30 Mar 2021 15:03:37
User opened query 'Per GCL Lab Reconciliation: Saliva: Re-query: Sample dated 22FEB2021 with Accession number 1F638125804 is reported under Illness Visit Day 28 in Preclarus portal, please review and update in EDC , to reflect correct with PPD central lab, if no sample collected on this day then please review the preclaus data and update the sample details to correct subject ID and visit in PPD portal, confirm the subject ID and visit in query response, thank you.' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 05:44:56

US3012329

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 21:53:26

Was Saliva Collected?

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation: Saliva Re-query : For Day 28, EDC Sample Collected is No, however in PPD Central Lab sample dated 22feb2021 (Accession # 1F638125804) is reported. Hence please confirm correct date of collection for Day 28 and update EDC or PPD Central lab.Please note that the collection details are required to be recorded for the subject irrespective of the results.' (Site from DM). User signature succeeded.	(b) (4), (b) (6) (b) (4)	30 Mar 2021 05:44:56
Query 'Per GCL Lab Reconciliation: Saliva Re-query : For Day 28, EDC Sample Collected is No, however in PPD Central Lab sample dated 22feb2021 (Accession # 1F638125804) is reported. Hence please confirm correct date of collection for Day 28 and update EDC or PPD Central lab.Please note that the collection details are required to be recorded for the subject irrespective of the results.' answered with 'No sample collected for this date' (Site from DM). User opened query 'Per GCL Lab Reconciliation: Saliva Re-query : For Day 28, EDC Sample Collected is No, however in PPD Central Lab sample dated 22feb2021 (Accession # 1F638125804) is reported. Hence please confirm correct date of collection for Day 28 and update EDC or PPD Central lab.Please note that the collection details are required to be recorded for the subject irrespective of the results.' (Site from DM). User entered 'No (N)'	Laurence Chu (b) (4) (b) (4) Pamela Fidler (b) (4) (b) (4), (b) (6) Jennifer Leyva (b) (4) (b) (4)	26 Mar 2021 01:15:03 19 Mar 2021 16:44:53 19 Mar 2021 12:04:31 10 Feb 2021 21:36:26

US3012329

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 21:53:26

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:05:34
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:19:25
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 15:00:49
Signature has been broken.	(b) (4)	
	Pamela Fidler (b) (4)	30 Mar 2021 15:03:37
User entered '22 Feb 2021' reason for change: Data Entry Error	Pamela Fidler (b) (4)	30 Mar 2021 15:03:37
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
	(b) (4)	
User entered empty.	Jennifer Leyva (b) (4)	10 Feb 2021 21:36:26
	(b) (4)	

US3012329

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:53:26

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:04:58
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User closed query 'Per ETRTR: Please complete data entry within Saliva Collection page, thanks.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	09 Mar 2021 19:43:22
Query 'Per ETRTR: Please complete data entry within Saliva Collection page, thanks.' answered with 'Done' (Site from CRA).	Pamela Fidler (b) (4)	03 Mar 2021 19:10:08
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 18:13:16
User opened query 'Per ETRTR: Please complete data entry within Saliva Collection page, thanks.' (Site from CRA).		09 Feb 2021 20:22:43
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	14 Jan 2021 20:10:11

US3012329

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:53:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:04:58
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:13:18
User entered '13 Jan 2021'	Jennifer Leyva (b) (4) (b) (4)	14 Jan 2021 20:10:11

US3012329

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:53:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:04:58
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:13:20
User entered 'Clinic (Clinic)'	Jennifer Leyva (b) (4) (b) (4)	14 Jan 2021 20:10:11

US3012329

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:53:26

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:04:58
User entered 'SICKD1'	System	14 Jan 2021 20:10:11

US3012329

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:53:26

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:05:02
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:14:32
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	14 Jan 2021 20:10:40

US3012329

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:53:26

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:05:02
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:14:32
User entered '13 Jan 2021'	Jennifer Leyva (b) (4) (b) (4)	14 Jan 2021 20:10:40

US3012329

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:53:26

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:05:02
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:14:32
User entered '11:20'	Jennifer Leyva (b) (4) (b) (4)	14 Jan 2021 20:10:40

US3012329

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:53:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:05:02
User entered '13 Jan 2021 11:20'	System	14 Jan 2021 20:10:40

US3012329

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:53:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:05:02
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:14:32
User entered '66.0' in	Jennifer Leyva (b) (4)	14 Jan 2021 20:10:40
DataPoint set to visible.	(b) (4) System	14 Jan 2021 20:10:11

US3012329

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:53:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:05:02
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:14:32
User entered '161.4' lb	Jennifer Leyva (b) (4)	14 Jan 2021 20:10:40
DataPoint set to visible.	(b) (4) System	14 Jan 2021 20:10:11

US3012329

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:53:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:05:02
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:14:32
User entered '98.1' F	Jennifer Leyva (b) (4) (b) (4)	14 Jan 2021 20:10:40

US3012329

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:53:26

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:05:02
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:14:32
User entered 'Oral (Oral)'	Jennifer Leyva (b) (4) (b) (4)	14 Jan 2021 20:10:40

US3012329

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:53:26

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:05:02
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:14:32
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	14 Jan 2021 20:10:40

US3012329

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:53:26

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:05:02
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:14:32
User entered '76'	Jennifer Leyva (b) (4) (b) (4)	14 Jan 2021 20:10:40

US3012329

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:53:26

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:05:02
User entered 'bpm'	System	14 Jan 2021 20:10:40

US3012329

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:53:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:05:02
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:14:32
User entered '14'	Jennifer Leyva (b) (4) (b) (4)	14 Jan 2021 20:10:40

US3012329

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:53:26

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:05:02
User entered 'breaths/min'	System	14 Jan 2021 20:10:40

US3012329

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:53:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:05:02
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:14:32
User entered '133'	Jennifer Leyva (b) (4) (b) (4)	14 Jan 2021 20:10:40

US3012329

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:53:26

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:05:02
User entered 'mmHg'	System	14 Jan 2021 20:10:40

US3012329

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:53:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:05:02
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:14:32
User entered '90'	Jennifer Leyva (b) (4) (b) (4)	14 Jan 2021 20:10:40

US3012329

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:53:26

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:05:02
User entered 'mmHg'	System	14 Jan 2021 20:10:40

US3012329

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:53:26

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:05:02

US3012329

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:53:26

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:05:02

US3012329

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:53:26

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:05:05
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:14:37
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	14 Jan 2021 20:10:46

US3012329

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:53:26

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:05:05
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:14:37
User entered '13 Jan 2021'	Jennifer Leyva (b) (4) (b) (4)	14 Jan 2021 20:10:46

US3012329

Folder: Illness Visit Day 1 (1)

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

Generated On: 11 Aug 2021 21:53:26

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:05:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:15:40
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	14 Jan 2021 20:10:57

US3012329

Folder: Illness Visit Day 1 (1)

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

Generated On: 11 Aug 2021 21:53:26

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:05:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:15:40
User closed query 'Per GCL Lab Recon: SARS-COV2: Sample dated 13 JAN 2021, is missing in PPD GCL records. Please confirm if site had scan in barcodes through Preclarus, so that the data reflects in PPD GCL records. If the sample has been shipped, please kindly provide the following data Accession number, Tracking number, shipping date in response, as this helps to track the sample with the details provided. Thank you.' (Site from DM).		02 Feb 2021 06:22:08
Query 'Per GCL Lab Recon: SARS-COV2: Sample dated 13 JAN 2021, is missing in PPD GCL records. Please confirm if site had scan in barcodes through Preclarus, so that the data reflects in PPD GCL records. If the sample has been shipped, please kindly provide the following data Accession number, Tracking number, shipping date in response, as this helps to track the sample with the details provided. Thank you.' answered with 'Accession Number: 1F60JCO Per Preclarus, sample received 19-Jan-2021' (Site from DM).	Jennifer Leyva (b) (4) (b) (4)	29 Jan 2021 14:38:40
User opened query 'Per GCL Lab Recon: SARS-COV2: Sample dated 13 JAN 2021, is missing in PPD GCL records. Please confirm if site had scan in barcodes through Preclarus, so that the data reflects in PPD GCL records. If the sample has been shipped, please kindly provide the following data Accession number, Tracking number, shipping date in response, as this helps to track the sample with the details provided. Thank you.' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 07:37:41
User entered '13 Jan 2021'	Jennifer Leyva (b) (4) (b) (4)	14 Jan 2021 20:10:57

US3012329

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:53:26

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:05:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:17:55
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered 'Yes (Y)'	Dean Skiles (b) (4)	23 Feb 2021 00:52:55

US3012329

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:53:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:05:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:17:55
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered '22 Feb 2021'	(b) (4) Dean Skiles (b) (4) (b) (4)	23 Feb 2021 00:52:55

US3012329

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:53:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:05:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:17:55
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered 'Clinic (Clinic)'	Dean Skiles (b) (4)	23 Feb 2021 00:52:55

US3012329

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:53:26

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:05:18
User entered 'SICKD28'	System	23 Feb 2021 00:52:55

US3012329

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:53:26

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:05:23
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:18
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered 'Yes (Y)'	Dean Skiles (b) (4)	23 Feb 2021 00:53:48

US3012329

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:53:26

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:05:23
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:18
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered '22 Feb 2021'	Dean Skiles (b) (4)	23 Feb 2021 00:53:48

US3012329

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:53:26

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:05:23
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:18
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered '16:54'	(b) (4) Dean Skiles (b) (4) (b) (4)	23 Feb 2021 00:53:48

US3012329

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:53:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:05:23
User entered '22 Feb 2021 16:54'	System	23 Feb 2021 00:53:48

US3012329

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:53:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:05:23
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:18
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered '66' in	(b) (4)	
	Dean Skiles (b) (4)	23 Feb 2021 00:53:48
	(b) (4)	
DataPoint set to visible.	System	23 Feb 2021 00:52:55

US3012329

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:53:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:05:23
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:18
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered '158.2' lb	Dean Skiles (b) (4)	23 Feb 2021 00:53:48
DataPoint set to visible.	System	23 Feb 2021 00:52:55

US3012329

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:53:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:05:23
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:18
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered '98.9' F	(b) (4) Dean Skiles (b) (4) (b) (4)	23 Feb 2021 00:53:48

US3012329

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:53:26

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:05:23
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:18
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered 'Oral (Oral)'	Dean Skiles (b) (4)	23 Feb 2021 00:53:48

US3012329

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:53:26

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:05:23
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:18
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered empty.	(b) (4) Dean Skiles (b) (4) (b) (4)	23 Feb 2021 00:53:48

US3012329

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:53:26

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:05:23
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:18
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered '97'	(b) (4) Dean Skiles (b) (4) (b) (4)	23 Feb 2021 00:53:48

US3012329

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:53:26

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:05:23
User entered 'bpm'	System	23 Feb 2021 00:53:48

US3012329

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:53:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:05:23
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:18
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered '12'	(b) (4) Dean Skiles (b) (4) (b) (4)	23 Feb 2021 00:53:48

US3012329

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:53:26

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:05:23
User entered 'breaths/min'	System	23 Feb 2021 00:53:48

US3012329

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:53:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:05:23
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:18
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered '140'	(b) (4) Dean Skiles (b) (4) (b) (4)	23 Feb 2021 00:53:48

US3012329

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:53:26

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:05:23
User entered 'mmHg'	System	23 Feb 2021 00:53:48

US3012329

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:53:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:05:23
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:18
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered '91'	(b) (4) Dean Skiles (b) (4) (b) (4)	23 Feb 2021 00:53:48

US3012329

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:53:26

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:05:23
User entered 'mmHg'	System	23 Feb 2021 00:53:48

US3012329

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:53:26

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:05:23

US3012329

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:53:26

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:05:23

US3012329

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:53:26

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:05:27
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:19:14
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered 'Yes (Y)'	Dean Skiles (b) (4)	23 Feb 2021 00:54:16

US3012329

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:53:26

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:05:27
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:19:14
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered '22 Feb 2021'	Dean Skiles (b) (4)	23 Feb 2021 00:54:16

US3012329

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 11 Aug 2021 21:53:26

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:05:30
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:35
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered 'Yes (Y)'	Dean Skiles (b) (4)	23 Feb 2021 00:54:36

US3012329

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 11 Aug 2021 21:53:26

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:05:30
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:35
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered '22 Feb 2021'	(b) (4) Dean Skiles (b) (4) (b) (4)	23 Feb 2021 00:54:36

US3012329

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

Form: Visit Date

Generated On: 11 Aug 2021 21:53:26

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:11:27
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered 'Yes (Y)'	(b) (4) Pamela Fidler (b) (4)	04 Mar 2021 01:04:42

US3012329

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

Form: Visit Date

Generated On: 11 Aug 2021 21:53:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:11:27
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered '03 Mar 2021'	(b) (4) Pamela Fidler (b) (4)	04 Mar 2021 01:04:42

US3012329

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

Form: Visit Date

Generated On: 11 Aug 2021 21:53:26

[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 10:11:27
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered 'Clinic (Clinic)'	Pamela Fidler (b) (4)	04 Mar 2021 01:04:42

US3012329

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

Form: Visit Date

Generated On: 11 Aug 2021 21:53:26

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:11:27
User entered 'UNBLND_DECIDE'	System	04 Mar 2021 01:04:42

US3012329

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

Form: Unblinding

Generated On: 11 Aug 2021 21:53:26

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:11:27
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered '03 Mar 2021'	(b) (4) Pamela Fidler (b) (4)	04 Mar 2021 01:04:59

US3012329

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

Form: Unblinding

Generated On: 11 Aug 2021 21:53:26

[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 10:11:27
User signature succeeded.	Laurence Chu (b) (4)	09 Apr 2021 20:47:50
User entered '0'	Jennifer Leyva (b) (4)	09 Apr 2021 15:16:19
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 09:07:46

US3012329

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

Form: Unblinding

Generated On: 11 Aug 2021 21:53:26

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:11:27
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered 'Yes (Y)'	(b) (4)	04 Mar 2021 01:04:59
	Pamela Fidler (b) (4)	

US3012329

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

Form: Unblinding

Generated On: 11 Aug 2021 21:53:26

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:11:27
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)	13 Apr 2021 16:01:54
	Laurence Chu (b) (4)	09 Apr 2021 20:47:50
	(b) (4)	
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 'Updated' (Site from DM).	Jennifer Leyva (b) (4)	09 Apr 2021 15:16:22
	(b) (4)	
User entered 'Amendment 6 or later (Amendment 6 or later)'	Jennifer Leyva (b) (4)	09 Apr 2021 15:16:19
	(b) (4)	
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). Amendment Manager inserted this DataPoint.	(b) (4), (b) (6)	09 Apr 2021 07:45:59
	System	06 Mar 2021 09:07:46

US3012329

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

Form: Unblinding

Generated On: 11 Aug 2021 21:53:26

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:11:27
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered '03 Mar 2021'	(b) (4) Pamela Fidler (b) (4)	04 Mar 2021 01:04:59

US3012329

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

Form: Unblinding

Generated On: 11 Aug 2021 21:53:26

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:11:27
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered 'Placebo (Placebo)'	(b) (4) Pamela Fidler (b) (4)	04 Mar 2021 01:04:59

US3012329

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

Form: Unblinding

Generated On: 11 Aug 2021 21:53:26

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:11:27
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered 'Placebo (Placebo)'	(b) (4) Pamela Fidler (b) (4)	04 Mar 2021 01:04:59

US3012329

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

Form: Unblinding

Generated On: 11 Aug 2021 21:53:26

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:11:27
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered 'Placebo (Placebo)'	(b) (4) Pamela Fidler (b) (4)	04 Mar 2021 01:04:59

US3012329

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

Form: Unblinding

Generated On: 11 Aug 2021 21:53:26

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:11:27
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered 'Yes (Y)'	(b) (4) Pamela Fidler (b) (4)	04 Mar 2021 01:04:59

US3012329

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

Form: Unblinding

Generated On: 11 Aug 2021 21:53:26

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:11:27
User entered '1'	System	04 Mar 2021 01:04:59

US3012329

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

Form: Unblinding

Generated On: 11 Aug 2021 21:53:26

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:11:27
User entered 'I'	System	04 Mar 2021 01:04:59

US3012329

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:53:26

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:11:27
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered '62.75' in	(b) (4) Pamela Fidler (b) (4)	04 Mar 2021 01:05:40

US3012329

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:53:26

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:11:27
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered '160.2' lb	(b) (4) Pamela Fidler (b) (4)	04 Mar 2021 01:05:40

US3012329

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:53:26

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:11:27
User entered '28.66454'	System	04 Mar 2021 01:05:40
DataPoint set to visible.	System	04 Mar 2021 01:04:59

US3012329

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:53:26

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:11:27
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered '62.75' in	(b) (4) Pamela Fidler (b) (4)	04 Mar 2021 01:05:40

US3012329

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:53:26

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:11:27
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered '160.2' lb	(b) (4) Pamela Fidler (b) (4)	04 Mar 2021 01:05:40

US3012329

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:53:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:11:27
User entered '28.66454'	System	04 Mar 2021 01:05:40
DataPoint set to visible.	System	04 Mar 2021 01:04:59

US3012329

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:53:26

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:11:27
User accepted default value 'Pre-Dose (PREDOSE)'	Pamela Fidler (b) (4)	04 Mar 2021 01:05:40

US3012329

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:53:26

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:11:27
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered 'Yes (Y)'	(b) (4) Pamela Fidler (b) (4)	04 Mar 2021 01:05:40

US3012329

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:53:26

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:11:27
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered '03 Mar 2021'	(b) (4) Pamela Fidler (b) (4)	04 Mar 2021 01:05:40

US3012329

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:53:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:11:27
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered '14:25'	(b) (4) Pamela Fidler (b) (4)	04 Mar 2021 01:05:40

US3012329

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:53:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:11:27
User entered '03 Mar 2021 14:25'	System	04 Mar 2021 01:05:40

US3012329

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:53:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:11:27
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered '98.2' F	(b) (4) Pamela Fidler (b) (4)	04 Mar 2021 01:05:40

US3012329

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:53:26

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:11:27
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered 'Oral (Oral)'	(b) (4) Pamela Fidler (b) (4)	04 Mar 2021 01:05:40

US3012329

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:53:26

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:11:27
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered empty.	(b) (4) Pamela Fidler (b) (4)	04 Mar 2021 01:05:40

US3012329

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:53:26

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:11:27
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered '83'	(b) (4) Pamela Fidler (b) (4)	04 Mar 2021 01:05:40

US3012329

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:53:26

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:11:27
User entered 'bpm'	System	04 Mar 2021 01:05:40

US3012329

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:53:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:11:27
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered '16'	(b) (4) Pamela Fidler (b) (4)	04 Mar 2021 01:05:40

US3012329

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:53:26

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:11:27
User entered 'breaths/min'	System	04 Mar 2021 01:05:40

US3012329

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:53:26

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:11:27
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered '131'	(b) (4) Pamela Fidler (b) (4)	04 Mar 2021 01:05:40

US3012329

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:53:26

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:11:27
User entered 'mmHg'	System	04 Mar 2021 01:05:40

US3012329

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:53:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:11:27
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered '79'	(b) (4) Pamela Fidler (b) (4)	04 Mar 2021 01:05:40

US3012329

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:53:26

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:11:27
User entered 'mmHg'	System	04 Mar 2021 01:05:40

US3012329

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:53:26

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:11:27
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered '62.75' in	(b) (4) Pamela Fidler (b) (4)	04 Mar 2021 01:05:40

US3012329

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:53:26

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:11:27
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered '160.2' lb	(b) (4) Pamela Fidler (b) (4)	04 Mar 2021 01:05:40

US3012329

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:53:26

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:11:27
User entered '28.66454'	System	04 Mar 2021 01:05:40
DataPoint set to visible.	System	04 Mar 2021 01:04:59

US3012329

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:53:26

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:11:27
User accepted default value 'Post-Dose (POSTDOSE)'	Pamela Fidler (b) (4)	04 Mar 2021 01:06:04

US3012329

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:53:26

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:11:27
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered 'Yes (Y)'	(b) (4) Pamela Fidler (b) (4)	04 Mar 2021 01:06:04

US3012329

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:53:26

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:11:27
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered '03 Mar 2021'	(b) (4) Pamela Fidler (b) (4)	04 Mar 2021 01:06:04

US3012329

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:53:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:11:27
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered '16:38'	(b) (4) Pamela Fidler (b) (4)	04 Mar 2021 01:06:04

US3012329

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:53:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:11:27
User entered '03 Mar 2021 16:38'	System	04 Mar 2021 01:06:04

US3012329

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:53:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:11:27
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered '98.1' F	(b) (4) Pamela Fidler (b) (4)	04 Mar 2021 01:06:04

US3012329

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:53:26

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:11:27
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered 'Oral (Oral)'	(b) (4) Pamela Fidler (b) (4)	04 Mar 2021 01:06:04

US3012329

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:53:26

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:11:27
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered empty.	(b) (4) Pamela Fidler (b) (4)	04 Mar 2021 01:06:04

US3012329

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:53:26

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:11:27
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered '70'	(b) (4) Pamela Fidler (b) (4)	04 Mar 2021 01:06:04

US3012329

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:53:26

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:11:27
User entered 'bpm'	System	04 Mar 2021 01:06:04

US3012329

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:53:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:11:27
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered '16'	(b) (4) Pamela Fidler (b) (4)	04 Mar 2021 01:06:04

US3012329

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:53:26

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:11:27
User entered 'breaths/min'	System	04 Mar 2021 01:06:04

US3012329

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:53:26

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:11:27
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered '134'	(b) (4) Pamela Fidler (b) (4)	04 Mar 2021 01:06:04

US3012329

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:53:26

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:11:27
User entered 'mmHg'	System	04 Mar 2021 01:06:04

US3012329

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:53:26

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:11:27
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered '82'	(b) (4) Pamela Fidler (b) (4)	04 Mar 2021 01:06:04

US3012329

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:53:26

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:11:27
User entered 'mmHg'	System	04 Mar 2021 01:06:04

US3012329

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

Form: Physical Examination

Generated On: 11 Aug 2021 21:53:26

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:11:27
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered 'Yes (Y)'	(b) (4) Pamela Fidler (b) (4)	04 Mar 2021 01:06:11

US3012329

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

Form: Physical Examination

Generated On: 11 Aug 2021 21:53:26

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:11:27
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered '03 Mar 2021'	Pamela Fidler (b) (4)	04 Mar 2021 01:06:11

US3012329

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

Form: Exposure

Generated On: 11 Aug 2021 21:53:26

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:11:27
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 18:38:27
User entered 'Yes (Y)'	Pamela Fidler (b) (4)	04 Mar 2021 01:06:28

US3012329

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

Form: Exposure

Generated On: 11 Aug 2021 21:53:26

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:11:27
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 18:38:27
User entered empty.	Pamela Fidler (b) (4)	04 Mar 2021 01:06:28

US3012329

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

Form: Exposure

Generated On: 11 Aug 2021 21:53:26

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)	27 Apr 2021 10:11:27
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 18:38:27
User entered empty.	Pamela Fidler (b) (4)	04 Mar 2021 01:06:28

US3012329

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

Form: Exposure

Generated On: 11 Aug 2021 21:53:26

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:11:27
User entered 'mRNA-1273'	System	04 Mar 2021 01:06:28
DataPoint set to visible.	System	04 Mar 2021 01:04:59

US3012329

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

Form: Exposure

Generated On: 11 Aug 2021 21:53:26

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:11:27
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 18:38:27
User entered '03 Mar 2021'	Pamela Fidler (b) (4)	04 Mar 2021 01:06:28

US3012329

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

Form: Exposure

Generated On: 11 Aug 2021 21:53:26

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:11:27
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 18:38:27
User entered '16:03'	Pamela Fidler (b) (4)	04 Mar 2021 01:06:28

US3012329

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

Form: Exposure

Generated On: 11 Aug 2021 21:53:26

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:11:27
User entered '03 Mar 2021 16:03'	System	04 Mar 2021 01:06:28

US3012329

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

Form: Exposure

Generated On: 11 Aug 2021 21:53:26

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:11:27
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 18:38:27
User entered 'Left Arm (LEFT ARM)'	Pamela Fidler (b) (4)	04 Mar 2021 01:06:28

US3012329

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

Form: Exposure

Generated On: 11 Aug 2021 21:53:26

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:11:27
DataPoint Verified.		18 Mar 2021 18:38:27
User entered 'ONCE'	System	04 Mar 2021 01:06:28

US3012329

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

Form: Exposure

Generated On: 11 Aug 2021 21:53:26

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:11:27
User entered 'INTRAMUSCULAR'	System	04 Mar 2021 01:06:28

US3012329

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:53:26

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:11:27
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered 'Yes (Y)'	(b) (4) Pamela Fidler (b) (4)	04 Mar 2021 01:06:37

US3012329

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:53:26

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:11:27
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered '03 Mar 2021'	(b) (4) Pamela Fidler (b) (4)	04 Mar 2021 01:06:37

US3012329

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:53:26

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:11:27
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered '15:22'	(b) (4) Pamela Fidler (b) (4)	04 Mar 2021 01:06:37

US3012329

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:53:26

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:11:27
User entered '03 Mar 2021 15:22'	System	04 Mar 2021 01:06:37

US3012329

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 21:53:26

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:11:27
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered 'Yes (Y)'	(b) (4) Pamela Fidler (b) (4)	04 Mar 2021 01:06:43

US3012329

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 21:53:26

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:11:27
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 03MAR2021 is recorded under Participant Decision Visit / OL-D1 in EDC, however, the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	10 Mar 2021 05:30:31
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 03MAR2021 is recorded under Participant Decision Visit / OL-D1 in EDC, however, the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' answered with '1f621731473' (Site from DM).	Pamela Fidler (b) (4)	08 Mar 2021 21:29:59
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 03MAR2021 is recorded under Participant Decision Visit / OL-D1 in EDC, however, the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 10:31:02
User entered '03 Mar 2021'	Pamela Fidler (b) (4)	04 Mar 2021 01:06:43

US3012329

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 21:53:26

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:11:27
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered '14:30'	(b) (4) Pamela Fidler (b) (4)	04 Mar 2021 01:06:43

US3012329

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 21:53:26

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:11:27
User entered '03 Mar 2021 14:30'	System	04 Mar 2021 01:06:43

US3012329

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

Form: Continuing

Generated On: 11 Aug 2021 21:53:26

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:11:27
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered 'Yes (Y)'	(b) (4) Pamela Fidler (b) (4)	04 Mar 2021 01:06:48

US3012329

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

Form: Continuing

Generated On: 11 Aug 2021 21:53:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:11:27
User entered 'I'	System	04 Mar 2021 01:06:48

US3012329

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:53:26

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:23:35
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:08
User entered 'Yes (Y)'	(b) (4)	11 Mar 2021 17:04:04
	(b) (4), (b) (6)	

US3012329

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:53:26

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:23:35
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:08
User entered '11 Mar 2021'	(b) (4)	11 Mar 2021 17:04:04
	(b) (4), (b) (6)	

US3012329

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:53:26

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:23:35
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:08
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 17:04:04

US3012329

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:53:26

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:23:35
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:08
User entered empty.	(b) (4), (b) (6)	11 Mar 2021 17:04:04

US3012329

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:53:26

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:23:35
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:08
User entered 'Yes (Y)'	(b) (4)	11 Mar 2021 17:04:07
	(b) (4), (b) (6)	

US3012329

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:53:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:23:35
User entered 'I'	System	11 Mar 2021 17:04:07

US3012329

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:53:26

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:23:35
User entered '1'	System	11 Mar 2021 17:04:07
DataPoint set to visible.	System	11 Mar 2021 17:04:07

US3012329

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:53:26

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 15:00:49
User entered 'Yes (Y)'	(b) (4) Pamela Fidler (b) (4)	29 Mar 2021 20:46:47

US3012329

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:53:26

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

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 15:00:49
User entered '29 Mar 2021'	(b) (4) Pamela Fidler (b) (4)	29 Mar 2021 20:46:47

US3012329

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:53:26

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

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 15:00:49
User entered 'Clinic (Clinic)'	(b) (4) Pamela Fidler (b) (4)	29 Mar 2021 20:46:47

US3012329

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:53:26

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'OLD29'	System	29 Mar 2021 20:46:47

US3012329

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:53:26

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Pamela Fidler (b) (4)	29 Mar 2021 20:47:08

US3012329

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:53:26

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 15:00:49
User entered 'Yes (Y)'	(b) (4) Pamela Fidler (b) (4)	29 Mar 2021 20:47:08

US3012329

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:53:26

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 15:00:49
User entered '29 Mar 2021'	(b) (4) Pamela Fidler (b) (4)	29 Mar 2021 20:47:08

US3012329

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:53:26

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 15:00:49
User entered '12:13'	(b) (4) Pamela Fidler (b) (4)	29 Mar 2021 20:47:08

US3012329

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:53:26

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

Audit	User	Time (GMT)
User entered '29 Mar 2021 12:13'	System	29 Mar 2021 20:47:08

US3012329

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:53:26

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 15:00:49
User entered '98.4' F	(b) (4) Pamela Fidler (b) (4)	29 Mar 2021 20:47:08

US3012329

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:53:26

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 15:00:49
User entered 'Oral (Oral)'	(b) (4) Pamela Fidler (b) (4)	29 Mar 2021 20:47:08

US3012329

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:53:26

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 15:00:49
User entered empty.	(b) (4) Pamela Fidler (b) (4)	29 Mar 2021 20:47:08

US3012329

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:53:26

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 15:00:49
User entered '77'	(b) (4) Pamela Fidler (b) (4)	29 Mar 2021 20:47:08

US3012329

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:53:26

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	29 Mar 2021 20:47:08

US3012329

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:53:26

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

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 15:00:49
User entered '14'	(b) (4) Pamela Fidler (b) (4)	29 Mar 2021 20:47:08

US3012329

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:53:26

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	29 Mar 2021 20:47:08

US3012329

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:53:26

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 15:00:49
User entered '126'	(b) (4) Pamela Fidler (b) (4)	29 Mar 2021 20:47:08

US3012329

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:53:26

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	29 Mar 2021 20:47:08

US3012329

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:53:26

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 15:00:49
User entered '83'	(b) (4) Pamela Fidler (b) (4)	29 Mar 2021 20:47:08

US3012329

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:53:26

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	29 Mar 2021 20:47:08

US3012329

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:53:26

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Pamela Fidler (b) (4) [REDACTED] [REDACTED]	29 Mar 2021 20:47:30

US3012329

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:53:26

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 15:00:49
User entered 'Yes (Y)'	(b) (4) Pamela Fidler (b) (4)	29 Mar 2021 20:47:30

US3012329

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:53:26

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 15:00:49
User entered '29 Mar 2021'	(b) (4) Pamela Fidler (b) (4)	29 Mar 2021 20:47:30

US3012329

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:53:26

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 15:00:49
User entered '13:22'	(b) (4) Pamela Fidler (b) (4)	29 Mar 2021 20:47:30

US3012329

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:53:26

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

Audit	User	Time (GMT)
User entered '29 Mar 2021 13:22'	System	29 Mar 2021 20:47:30

US3012329

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:53:26

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 15:00:49
User entered '98.9' F	(b) (4) Pamela Fidler (b) (4)	29 Mar 2021 20:47:30

US3012329

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:53:26

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 15:00:49
User entered 'Oral (Oral)'	(b) (4) Pamela Fidler (b) (4)	29 Mar 2021 20:47:30

US3012329

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:53:26

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 15:00:49
User entered empty.	(b) (4) Pamela Fidler (b) (4)	29 Mar 2021 20:47:30

US3012329

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:53:26

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 15:00:49
User entered '73'	(b) (4) Pamela Fidler (b) (4)	29 Mar 2021 20:47:30

US3012329

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:53:26

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	29 Mar 2021 20:47:30

US3012329

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:53:26

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

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 15:00:49
User entered '14'	(b) (4) Pamela Fidler (b) (4)	29 Mar 2021 20:47:30

US3012329

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:53:26

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	29 Mar 2021 20:47:30

US3012329

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:53:26

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 15:00:49
User entered '137'	(b) (4) Pamela Fidler (b) (4)	29 Mar 2021 20:47:30

US3012329

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:53:26

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	29 Mar 2021 20:47:30

US3012329

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:53:26

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 15:00:49
User entered '84'	(b) (4) Pamela Fidler (b) (4)	29 Mar 2021 20:47:30

US3012329

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:53:26

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	29 Mar 2021 20:47:30

US3012329

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:53:26

Was the physical examination performed?

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 15:00:49
User entered 'Yes (Y)'	(b) (4) Pamela Fidler (b) (4)	29 Mar 2021 20:47:37

US3012329

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:53:26

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 15:00:49
User entered '29 Mar 2021'	(b) (4) Pamela Fidler (b) (4)	29 Mar 2021 20:47:37

US3012329

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:53:26

[Was study treatment given?](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 15:00:49
User entered 'Yes (Y)'	(b) (4) Pamela Fidler (b) (4)	29 Mar 2021 20:47:47

US3012329

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:53:26

[If No, reason not given](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 15:00:49
User entered empty.	(b) (4) Pamela Fidler (b) (4)	29 Mar 2021 20:47:47

US3012329

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:53:26

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

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 15:00:49
User entered empty.	(b) (4) Pamela Fidler (b) (4)	29 Mar 2021 20:47:47

US3012329

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:53:26

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
User entered 'mRNA-1273'	System	29 Mar 2021 20:47:47
DataPoint set to visible.	System	11 Mar 2021 17:04:07

US3012329

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:53:26

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 15:00:49
User entered '29 Mar 2021'	(b) (4) Pamela Fidler (b) (4)	29 Mar 2021 20:47:47

US3012329

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:53:26

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 15:00:49
User entered '12:47'	(b) (4) Pamela Fidler (b) (4)	29 Mar 2021 20:47:47

US3012329

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:53:26

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '29 Mar 2021 12:47'	System	29 Mar 2021 20:47:47

US3012329

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:53:26

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 15:00:49
User entered 'Left Arm (LEFT ARM)'	(b) (4) Pamela Fidler (b) (4)	29 Mar 2021 20:47:47

US3012329

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:53:26

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
User entered 'ONCE'	System	29 Mar 2021 20:47:47

US3012329

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:53:26

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	29 Mar 2021 20:47:47

US3012329

Folder: OL-D29 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:53:26

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 15:00:49
User entered 'Yes (Y)'	(b) (4) Pamela Fidler (b) (4)	29 Mar 2021 20:47:49

US3012329

Folder: OL-D29 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:53:26

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	29 Mar 2021 20:47:49

US3012329

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:53:26

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 15:00:49
User entered 'Yes (Y)'	(b) (4) Jessica Ruff (b) (4) (b) (4)	06 Apr 2021 20:57:08

US3012329

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:53:26

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 15:00:49
User entered '6 Apr 2021'	(b) (4) Jessica Ruff (b) (4) (b) (4)	06 Apr 2021 20:57:08

US3012329

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:53:26

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 15:00:49
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Jessica Ruff (b) (4) (b) (4)	06 Apr 2021 20:57:08

US3012329

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:53:26

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 15:00:49
User entered empty.	(b) (4) Jessica Ruff (b) (4) (b) (4)	06 Apr 2021 20:57:08

US3012329

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:53:26

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 15:00:49
User entered 'Yes (Y)'	(b) (4) Jessica Ruff (b) (4) (b) (4)	06 Apr 2021 20:57:10

US3012329

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:53:26

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	06 Apr 2021 20:57:10

US3012329

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:53:26

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	30 Apr 2021 15:32:10
User entered 'Yes (Y)'	(b) (4) Dean Skiles (b) (4) (b) (4)	29 Apr 2021 23:28:14

US3012329

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:53:26

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

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	30 Apr 2021 15:32:10
User entered '29 Apr 2021'	(b) (4) Dean Skiles (b) (4) (b) (4)	29 Apr 2021 23:28:14

US3012329

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:53:26

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

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	30 Apr 2021 15:32:10
User entered 'Clinic (Clinic)'	(b) (4) Dean Skiles (b) (4) (b) (4)	29 Apr 2021 23:28:14

US3012329

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:53:26

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'OLD57'	System	29 Apr 2021 23:28:14

US3012329

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:53:26

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	30 Apr 2021 15:32:10
User entered 'Yes (Y)'	(b) (4) Dean Skiles (b) (4) (b) (4)	29 Apr 2021 23:29:31

US3012329

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:53:26

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	30 Apr 2021 15:32:10
User entered '29 Apr 2021'	(b) (4) Dean Skiles (b) (4) (b) (4)	29 Apr 2021 23:29:31

US3012329

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:53:26

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	30 Apr 2021 15:32:10
User entered '16:51'	(b) (4) Dean Skiles (b) (4) (b) (4)	29 Apr 2021 23:29:31

US3012329

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:53:26

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

Audit	User	Time (GMT)
User entered '29 Apr 2021 16:51'	System	29 Apr 2021 23:29:31

US3012329

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:53:26

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	30 Apr 2021 15:32:10
User entered '98.5' F	(b) (4) Dean Skiles (b) (4) (b) (4)	29 Apr 2021 23:29:31

US3012329

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:53:26

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	30 Apr 2021 15:32:10
User entered 'Oral (Oral)'	(b) (4) Dean Skiles (b) (4) (b) (4)	29 Apr 2021 23:29:31

US3012329

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:53:26

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	30 Apr 2021 15:32:10
User entered empty.	(b) (4) Dean Skiles (b) (4) (b) (4)	29 Apr 2021 23:29:31

US3012329

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:53:26

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	30 Apr 2021 15:32:10
User entered '89'	(b) (4) Dean Skiles (b) (4) (b) (4)	29 Apr 2021 23:29:31

US3012329

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:53:26

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	29 Apr 2021 23:29:31

US3012329

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:53:26

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

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	30 Apr 2021 15:32:10
User entered '16'	(b) (4) Dean Skiles (b) (4) (b) (4)	29 Apr 2021 23:29:31

US3012329

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:53:26

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	29 Apr 2021 23:29:31

US3012329

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:53:26

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

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	30 Apr 2021 15:32:10
User entered '139'	(b) (4) Dean Skiles (b) (4) (b) (4)	29 Apr 2021 23:29:31

US3012329

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:53:26

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	29 Apr 2021 23:29:31

US3012329

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:53:26

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

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	30 Apr 2021 15:32:10
User entered '84'	(b) (4) Dean Skiles (b) (4) (b) (4)	29 Apr 2021 23:29:31

US3012329

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:53:26

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	29 Apr 2021 23:29:31

US3012329

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:53:26

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	30 Apr 2021 15:32:10
User entered 'No (N)'	(b) (4) Dean Skiles (b) (4) (b) (4)	29 Apr 2021 23:29:58

US3012329

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:53:26

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	30 Apr 2021 15:32:10
User entered empty.	(b) (4) Dean Skiles (b) (4) (b) (4)	29 Apr 2021 23:29:58

US3012329

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:53:26

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	30 Apr 2021 15:32:10
User entered 'Yes (Y)'	(b) (4) Dean Skiles (b) (4) (b) (4)	29 Apr 2021 23:30:30

US3012329

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:53:26

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	30 Apr 2021 15:32:10
User entered '29 Apr 2021'	(b) (4) Dean Skiles (b) (4) (b) (4)	29 Apr 2021 23:30:30

US3012329

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:53:26

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	30 Apr 2021 15:32:10
User entered '16:57'	(b) (4) Dean Skiles (b) (4) (b) (4)	29 Apr 2021 23:30:30

US3012329

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:53:26

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '29 Apr 2021 16:57'	System	29 Apr 2021 23:30:30

US3012329

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 11 Aug 2021 21:53:26

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:04:01
User signature succeeded.	Laurence Chu (b) (4)	12 Mar 2021 19:42:47
DataPoint Verified.	(b) (4)	11 Feb 2021 18:15:53
User entered 'Yes (Y)' reason for change: New Information	Jennifer Leyva (b) (4)	20 Jan 2021 00:27:50
User entered 'No (N)'	Jennifer Leyva (b) (4)	17 Sep 2020 21:43:40

US3012329

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:53:26

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	12 Mar 2021 19:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:16:15
Reviewed for Safety.		20 Jan 2021 13:26:55
User entered 'USA-US006-2021-mRNA-1273-P301000003'	System	20 Jan 2021 13:26:52
User entered 'New'	(b) (4), (b) (6)	20 Jan 2021 13:26:52

US3012329

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:53:26

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	12 Mar 2021 19:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 19:39:23
User closed query 'Per CDM: Per CCGs, confirmed symptomatic Covid-19 cases should be reported as either "Covid-19" or "Symptomatic Covid-19". Please update accordingly. ' (Site from DM).		04 Mar 2021 05:57:37
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Mar 2021 19:06:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Mar 2021 19:06:44
Data point term sent to Coder	System	03 Mar 2021 19:05:31
Query 'Per CDM: Per CCGs, confirmed symptomatic Covid-19 cases should be reported as either "Covid-19" or "Symptomatic Covid-19". Please update accordingly. ' answered with 'updated' (Site from DM).	Pamela Fidler (b) (4)	03 Mar 2021 19:05:31
DataPoint Un-verified.	Pamela Fidler (b) (4)	03 Mar 2021 19:05:08
Coding entries removed.	Pamela Fidler (b) (4)	03 Mar 2021 19:05:08
User entered 'COVID-19' reason for change: Data Entry Error	Pamela Fidler (b) (4)	03 Mar 2021 19:05:08
User opened query 'Per CDM: Per CCGs, confirmed symptomatic Covid-19 cases should be reported as either "Covid-19" or "Symptomatic Covid-19". Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	12 Feb 2021 13:00:14
DataPoint Verified.		11 Feb 2021 18:16:15
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Jan 2021 00:30:11
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Jan 2021 00:30:11
Data point term sent to Coder	System	20 Jan 2021 00:29:20

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:53:26

[Adverse event](#)

Audit	User	Time (GMT)
User entered 'COVID-19 Infection'	Jennifer Leyva (b) (4) (b) (4)	20 Jan 2021 00:28:40

US3012329

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:53:26

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	12 Mar 2021 19:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:16:15
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	20 Jan 2021 00:28:40

US3012329

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:53:26

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	12 Mar 2021 19:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:16:15
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	20 Jan 2021 00:28:40

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:53:26

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	12 Mar 2021 19:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:16:15
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	20 Jan 2021 00:28:40

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:53:26

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	12 Mar 2021 19:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 19:39:20
User closed query 'PV Query: Start date of event is reported as 25 Jan 2021. COVID-19 symptoms have been reported starting on 11 Jan 2021. Please update the event start date to reflect the date that the subject first experienced symptoms, as per the protocol. ' (Site from Safety).		12 Feb 2021 17:27:52
DataPoint Un-verified.		11 Feb 2021 18:17:18
DataPoint Verified.		11 Feb 2021 18:16:15
Query 'PV Query: Start date of event is reported as 25 Jan 2021. COVID-19 symptoms have been reported starting on 11 Jan 2021. Please update the event start date to reflect the date that the subject first experienced symptoms, as per the protocol. ' answered with 'Updated' (Site from Safety).	Jennifer Leyva (b) (4) (b) (4)	03 Feb 2021 22:08:05
User entered '11 Jan 2021' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	03 Feb 2021 22:07:18
User opened query 'PV Query: Start date of event is reported as 25 Jan 2021. COVID-19 symptoms have been reported starting on 11 Jan 2021. Please update the event start date to reflect the date that the subject first experienced symptoms, as per the protocol. ' (Site from Safety).	(b) (4), (b) (6)	03 Feb 2021 16:50:20
User closed query 'PV Query: COVID-19 symptoms have been reported starting on 11 Jan 2021. Please update the event start date to reflect the date that the subject first experienced symptoms, as per the protocol.' (Site from Safety).		28 Jan 2021 21:35:21
User entered '25 Jan 2021' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	28 Jan 2021 20:11:03
Query 'PV Query: COVID-19 symptoms have been reported starting on 11 Jan 2021. Please update the event start date to reflect the date that the subject first experienced symptoms, as per the protocol.' answered with 'Updated' (Site from Safety).	Jennifer Leyva (b) (4) (b) (4)	28 Jan 2021 16:58:53
User entered '11 Jan 2021' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	28 Jan 2021 16:58:12

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:53:26

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'PV Query: COVID-19 symptoms have been reported starting on 11 Jan 2021. Please update the event start date to reflect the date that the subject first experienced symptoms, as per the protocol.' (Site from Safety). User entered '13 Jan 2021'	(b) (4), (b) (6) Jennifer Leyva (b) (4) (b) (4)	28 Jan 2021 15:57:02 20 Jan 2021 00:28:40

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:53:26

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	12 Mar 2021 19:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:16:15
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	20 Jan 2021 00:28:40

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:53:26

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Jan 2021 00:28:40

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:53:26

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	15 Apr 2021 16:38:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 20:34:16
User closed query 'Per source, end date of AE is recorded as, 25-Jan-2021. Please verify and update EDC accordingly.' (Site from CRA).		14 Apr 2021 20:34:15
Query 'Per source, end date of AE is recorded as, 25-Jan-2021. Please verify and update EDC accordingly.' answered with 'Updated' (Site from CRA).	Pamela Fidler (b) (4)	13 Apr 2021 18:20:18
Signature has been broken.	Pamela Fidler (b) (4)	13 Apr 2021 18:20:01
User entered 'No (N)' reason for change: Data Entry Error	Pamela Fidler (b) (4)	13 Apr 2021 18:20:01
User opened query 'Per source, end date of AE is recorded as, 25-Jan-2021. Please verify and update EDC accordingly.' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 17:28:30
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 15:00:49
DataPoint Un-verified.	(b) (4)	
	Jennifer Leyva (b) (4)	06 Apr 2021 20:52:13
Signature has been broken.	(b) (4)	
	Jennifer Leyva (b) (4)	06 Apr 2021 20:52:13
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	Jennifer Leyva (b) (4)	06 Apr 2021 20:52:13
User signature succeeded.	Laurence Chu (b) (4)	12 Mar 2021 19:42:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Feb 2021 18:16:15
User entered 'No (N)' reason for change: New Information	Jennifer Leyva (b) (4)	27 Jan 2021 20:08:23
User entered 'Yes (Y)'	(b) (4)	
	Jennifer Leyva (b) (4)	20 Jan 2021 00:28:40
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:53:26

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'PV Query:: Please clarify event end date considering that the subject visited the ER and received treatment on 25Jan2021 with symptoms of shortness of breath and chest pain. ' canceled (Site from Safety).	(b) (4), (b) (6)	28 Apr 2021 23:50:30
User opened query 'PV Query:: Please clarify event end date considering that the subject visited the ER and received treatment on 25Jan2021 with symptoms of shortness of breath and chest pain. ' (Site from Safety).		28 Apr 2021 23:49:51
User signature succeeded.	Laurence Chu (b) (4)	15 Apr 2021 16:38:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 20:34:18
Signature has been broken.	Pamela Fidler (b) (4)	13 Apr 2021 18:20:01
User entered '25 Jan 2021' reason for change: Data Entry Error	Pamela Fidler (b) (4)	13 Apr 2021 18:20:01
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 15:00:49
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	06 Apr 2021 20:52:42
Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered by data change (Site from System).	System	06 Apr 2021 20:52:42
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	06 Apr 2021 20:52:13
DataPoint Un-verified.	Jennifer Leyva (b) (4)	06 Apr 2021 20:52:13
Signature has been broken.	Jennifer Leyva (b) (4)	06 Apr 2021 20:52:13
User entered empty; reason for change Data Entry Error	Jennifer Leyva (b) (4)	06 Apr 2021 20:52:13
User signature succeeded.	Laurence Chu (b) (4)	12 Mar 2021 19:42:47
User closed query 'Per source, end date is listed as 25-Jan-2021. Please review and reconcile.' (Site from CRA).	(b) (4), (b) (6)	09 Mar 2021 19:40:06

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:53:26

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 19:39:57
Query 'Per source, end date is listed as 25-Jan-2021. Please review and reconcile. ' answered with 'updated' (Site from CRA).	Pamela Fidler (b) (4)	03 Mar 2021 19:06:36
User entered '25 Jan 2021' reason for change: New Information	Pamela Fidler (b) (4)	03 Mar 2021 19:06:28
DataPoint Un-verified.	(b) (4), (b) (6)	11 Feb 2021 18:18:30
User opened query 'Per source, end date is listed as 25-Jan-2021. Please review and reconcile. ' (Site from CRA).		11 Feb 2021 18:18:28
DataPoint Verified.		11 Feb 2021 18:16:15
User entered '27 Jan 2021' reason for change: New Information	Jennifer Leyva (b) (4)	27 Jan 2021 20:08:23
User entered empty.	Jennifer Leyva (b) (4)	20 Jan 2021 00:28:40

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:53:26

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	12 Mar 2021 19:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:16:15
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	20 Jan 2021 00:28:40

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:53:26

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Query 'PV Query:Please clarify event end date considering that the subject visited the ER and received treatment on 25Jan2021 with symptoms of shortness of breath and chest pain.' canceled (Site from Safety).	(b) (4), (b) (6)	28 Apr 2021 00:22:41
User opened query 'PV Query:Please clarify event end date considering that the subject visited the ER and received treatment on 25Jan2021 with symptoms of shortness of breath and chest pain.' (Site from Safety).		15 Mar 2021 16:35:29
User entered empty.	System	20 Jan 2021 00:28:40

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:53:26

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	12 Mar 2021 19:42:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Feb 2021 18:16:15
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Jennifer Leyva (b) (4)	03 Feb 2021 22:28:03
reason for change: New Information	(b) (4)	
User entered 'Grade 3/Severe (Grade 3/Severe)'	Jennifer Leyva (b) (4)	28 Jan 2021 20:11:03
reason for change: New Information	(b) (4)	
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Jennifer Leyva (b) (4)	20 Jan 2021 00:28:40
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:53:26

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	12 Mar 2021 19:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:16:15
User entered 'No (N)' reason for change: New Information	Jennifer Leyva (b) (4) (b) (4)	03 Feb 2021 22:28:03
User entered 'Yes (Y)' reason for change: New Information	Jennifer Leyva (b) (4) (b) (4)	28 Jan 2021 20:11:03
User closed query 'Is the adverse event serious is No, System but seriousness criteria is provided. Please correct.' (Site from System).		27 Jan 2021 20:08:04
User opened query 'Is the adverse event serious is No, but seriousness criteria is provided. Please correct.' (Site from System).	System	27 Jan 2021 20:07:35
User entered 'No (N)' reason for change: New Information	Jennifer Leyva (b) (4) (b) (4)	27 Jan 2021 20:07:35
User entered 'Yes (Y)' reason for change: New Information	Jennifer Leyva (b) (4) (b) (4)	27 Jan 2021 18:01:47
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	20 Jan 2021 00:28:40

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:53:26

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	12 Mar 2021 19:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:16:15
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	20 Jan 2021 00:28:40

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:53:26

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	12 Mar 2021 19:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:16:15
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	20 Jan 2021 00:28:40

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:53:26

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	12 Mar 2021 19:42:47
DataPoint Verified.	(b) (4)	11 Feb 2021 18:16:15
	(b) (4), (b) (6)	
User entered '0' reason for change: New Information	Jennifer Leyva (b) (4)	03 Feb 2021 22:28:03
	(b) (4)	
User entered '1' reason for change: New Information	Jennifer Leyva (b) (4)	28 Jan 2021 20:11:03
	(b) (4)	
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	28 Jan 2021 06:59:39
User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).		28 Jan 2021 06:59:37
Query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered with 'Redacted. See SAE (AE #2)' (Site from System).	Jennifer Leyva (b) (4)	27 Jan 2021 20:11:27
	(b) (4)	
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	27 Jan 2021 20:08:04
User entered '0' reason for change: New Information	Jennifer Leyva (b) (4)	27 Jan 2021 20:08:04
	(b) (4)	
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'No discharge date yet as subject is currently hospitalized' (Site from System).	Jennifer Leyva (b) (4)	27 Jan 2021 18:02:13
	(b) (4)	
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	27 Jan 2021 18:01:47
User entered '1' reason for change: New Information	Jennifer Leyva (b) (4)	27 Jan 2021 18:01:47
	(b) (4)	
User entered '0'	Jennifer Leyva (b) (4)	20 Jan 2021 00:28:40
	(b) (4)	

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Folder: Adverse Events

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Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	12 Mar 2021 19:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:16:15
User entered empty; reason for change New Information	Jennifer Leyva (b) (4) (b) (4)	03 Feb 2021 22:28:03
User entered '25 Jan 2021' reason for change: New Information	Jennifer Leyva (b) (4) (b) (4)	28 Jan 2021 20:11:03
User entered '20 Jan 2021' reason for change: New Information	Jennifer Leyva (b) (4) (b) (4)	27 Jan 2021 18:01:47
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	20 Jan 2021 00:28:40

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:53:26

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	12 Mar 2021 19:42:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Feb 2021 18:16:15
User entered empty; reason for change New Information	Jennifer Leyva (b) (4)	03 Feb 2021 22:28:03
User entered '26 Jan 2021' reason for change: New Information	Jennifer Leyva (b) (4)	28 Jan 2021 20:11:03
User entered empty.	Jennifer Leyva (b) (4)	20 Jan 2021 00:28:40

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Folder: Adverse Events

Form: Adverse Events (1)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	12 Mar 2021 19:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:16:15
User entered empty; reason for change Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	03 Feb 2021 22:28:03
User entered 'No (N)' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	28 Jan 2021 20:11:03
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	20 Jan 2021 00:28:40

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Form: Adverse Events (1)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	12 Mar 2021 19:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:16:15
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	20 Jan 2021 00:28:40

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:53:26

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	12 Mar 2021 19:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:16:15
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	20 Jan 2021 00:28:40

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:53:26

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	12 Mar 2021 19:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:16:15
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	20 Jan 2021 00:28:40

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Folder: Adverse Events

Form: Adverse Events (1)

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	12 Mar 2021 19:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:16:15
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	20 Jan 2021 00:28:40

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Folder: Adverse Events

Form: Adverse Events (1)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	12 Mar 2021 19:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:16:15
User entered 'Not Related (NOT RELATED)'	Jennifer Leyva (b) (4) (b) (4)	20 Jan 2021 00:28:40

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:53:26

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	12 Mar 2021 19:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:16:15
User entered 'Not Related (NOT RELATED)'	Jennifer Leyva (b) (4) (b) (4)	20 Jan 2021 00:28:40

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	12 Mar 2021 19:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:16:15
User entered 'Not Applicable (NOT APPLICABLE)'	Jennifer Leyva (b) (4) (b) (4)	20 Jan 2021 00:28:40

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[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	12 Mar 2021 19:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:16:15
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	20 Jan 2021 00:28:40

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:53:26

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	12 Mar 2021 19:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:16:15
User entered 'I'	Jennifer Leyva (b) (4) (b) (4)	20 Jan 2021 00:28:40

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Folder: Adverse Events

Form: Adverse Events (1)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	12 Mar 2021 19:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:16:15
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	20 Jan 2021 00:28:40

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Folder: Adverse Events

Form: Adverse Events (1)

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[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	15 Apr 2021 16:38:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 20:34:24
User closed query 'Per source, outcome listed as, Recovered/Resolved. Please verify and update EDC accordingly.' (Site from CRA).		14 Apr 2021 20:34:23
Query 'Per source, outcome listed as, Recovered/Resolved. Please verify and update EDC accordingly.' answered with 'Updated' (Site from CRA).	Pamela Fidler (b) (4)	13 Apr 2021 18:20:34
Signature has been broken.	Pamela Fidler (b) (4)	13 Apr 2021 18:20:01
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Pamela Fidler (b) (4)	13 Apr 2021 18:20:01
User opened query 'Per source, outcome listed as, Recovered/Resolved. Please verify and update EDC accordingly.' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 17:29:09
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 15:00:49
DataPoint Un-verified.	Jennifer Leyva (b) (4)	06 Apr 2021 20:52:42
Signature has been broken.	Jennifer Leyva (b) (4)	06 Apr 2021 20:52:42
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	Jennifer Leyva (b) (4)	06 Apr 2021 20:52:42
User signature succeeded.	Laurence Chu (b) (4)	12 Mar 2021 19:42:47
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 18:16:15
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Jennifer Leyva (b) (4)	27 Jan 2021 20:08:23
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Jennifer Leyva (b) (4)	20 Jan 2021 00:28:40

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Form: Adverse Events (1)

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	12 Mar 2021 19:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:16:15
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	20 Jan 2021 00:28:40

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	12 Mar 2021 19:42:47
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results performed during the hospitalization. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response. ' (Site from Safety). User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so ' (Site from Safety). DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:28:14 12 Feb 2021 17:28:04 11 Feb 2021 18:16:15
User entered 'SUBJECT REPORTED TO ER ON 25-JAN-2021 WITH SHORTNESS OF BREATH AND CHEST PAIN, WAS TREATED AND RELEASED AFTER 4 HOURS. CON-MEDS USED TO TREAT ENTERED.	Jennifer Leyva (b) (4) (b) (4)	03 Feb 2021 22:29:07
RECORDS FROM HOSPITAL RECEIVED AND SUBJECT WAS NOT ADMITTED.' reason for change: Data Entry Error Query 'PV Query: Please provide any relevant laboratory and diagnostic test results performed during the hospitalization. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response. ' answered with 'Records were received and state that subject was NOT admitted and was discharged after 4 hours in the ER. Therefore this is actually NOT an SAE. ' (Site from Safety).	Jennifer Leyva (b) (4) (b) (4)	03 Feb 2021 22:27:29

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so ' answered with 'COVID testing not done. ' (Site from Safety).	Jennifer Leyva (b) (4)	03 Feb 2021 22:08:33
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results performed during the hospitalization. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response. ' (Site from Safety).	(b) (4), (b) (6)	03 Feb 2021 16:51:36
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so ' (Site from Safety).		03 Feb 2021 16:51:02
User closed query ' PV Query: It was reported the subject was tested for COVID-19 on 13 Jan 2021, please provide results. If not, please explain.' (Site from Safety).		28 Jan 2021 21:35:10
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	28 Jan 2021 20:11:29
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	28 Jan 2021 20:11:29
User entered 'SUBJECT REPORTED TO ER ON 25-JAN-2021 WITH SHORTNESS OF BREATH AND CHEST PAIN AND WAS ADMITTED, TREATED AND RELEASED ON 26-JAN-2021. CON-MEDS USED TO TREAT ENTERED. HOSPITAL AND DISCHARGE RECORDS PENDING.' reason for change: Data Entry Error	Jennifer Leyva (b) (4)	28 Jan 2021 20:11:29
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	28 Jan 2021 20:11:03

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
Query ' PV Query: It was reported the subject was tested for COVID-19 on 13 Jan 2021, please provide results. If not, please explain.' answered with 'Correct. This test is entered in COVID Diagnostic Test page under COVID-19 Assessment 12 Jan 2021 folder.' (Site from Safety).	Jennifer Leyva (b) (4) (b) (4)	28 Jan 2021 16:59:25
User opened query ' PV Query: It was reported the subject was tested for COVID-19 on 13 Jan 2021, please provide results. If not, please explain.' (Site from Safety).	(b) (4), (b) (6)	28 Jan 2021 15:57:47
User entered empty; reason for change Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	27 Jan 2021 20:07:45
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	27 Jan 2021 18:03:30
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	27 Jan 2021 18:03:30
User entered 'Subject reported to hospital on 20-Jan-2021 due to difficulty breathing. Was given medications (entered in CM page) and released but returned same day due to no improvement and has been hospitalized since. Pending records.' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	27 Jan 2021 18:03:30
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	27 Jan 2021 18:01:47
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	20 Jan 2021 00:28:40

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Folder: Adverse Events

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[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	03 Feb 2021 22:28:03
User entered '1'	System	28 Jan 2021 20:11:03
User entered '0'	System	27 Jan 2021 20:07:35
User entered '1'	System	27 Jan 2021 18:01:47
User entered '0'	System	20 Jan 2021 00:28:40

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Folder: Adverse Events

Form: Adverse Events (1)

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[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	20 Jan 2021 00:28:40

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:53:26

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	28 Jan 2021 20:11:03

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Folder: Adverse Events

Form: Adverse Events (3)

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[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:05:11

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:53:26

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:05:11
User signature succeeded.	Laurence Chu (b) (4)	12 Mar 2021 19:42:47
	(b) (4)	
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Urinary tract infections, PT: Urinary tract infection, LLT: Urinary tract infection - version MedDRA\\23.0.	Coder Import (b) (4)	11 Mar 2021 17:06:53
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Mar 2021 17:06:53
	(b) (4)	
Data point term sent to Coder	System	11 Mar 2021 17:05:56
User entered 'urinary tract infection'	(b) (4), (b) (6)	11 Mar 2021 17:05:26

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:53:26

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:05:11
User signature succeeded.	Laurence Chu (b) (4)	12 Mar 2021 19:42:47
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	11 Mar 2021 17:05:26

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:53:26

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:05:11
User signature succeeded.	Laurence Chu (b) (4)	12 Mar 2021 19:42:47
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	11 Mar 2021 17:05:26

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Folder: Adverse Events

Form: Adverse Events (3)

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:05:11
User signature succeeded.	Laurence Chu (b) (4)	12 Mar 2021 19:42:47
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	11 Mar 2021 17:05:26

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Folder: Adverse Events

Form: Adverse Events (3)

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:05:11
User signature succeeded.	Laurence Chu (b) (4)	12 Mar 2021 19:42:47
	(b) (4)	
User entered '7 Mar 2021'	(b) (4), (b) (6)	11 Mar 2021 17:05:26

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Folder: Adverse Events

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[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:05:11
User signature succeeded.	Laurence Chu (b) (4)	12 Mar 2021 19:42:47
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	11 Mar 2021 17:05:26

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[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:05:11
User entered empty.	System	11 Mar 2021 17:05:26

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Folder: Adverse Events

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[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:05:11
User signature succeeded.	Laurence Chu (b) (4)	12 Mar 2021 19:42:47
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	11 Mar 2021 17:05:26

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Folder: Adverse Events

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)	28 Apr 2021 10:05:11
User signature succeeded.	Laurence Chu (b) (4)	12 Mar 2021 19:42:47
	(b) (4)	
User entered '11 Mar 2021'	(b) (4), (b) (6)	11 Mar 2021 17:05:26

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:53:26

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:05:11
User signature succeeded.	Laurence Chu (b) (4)	12 Mar 2021 19:42:47
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	11 Mar 2021 17:05:26

US3012329

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:53:26

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:05:11
User entered empty.	System	11 Mar 2021 17:05:26

US3012329

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:53:26

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:05:11
User signature succeeded.	Laurence Chu (b) (4)	12 Mar 2021 19:42:47
	(b) (4)	
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4), (b) (6)	11 Mar 2021 17:05:26

US3012329

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:53:26

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:05:11
User signature succeeded.	Laurence Chu (b) (4)	12 Mar 2021 19:42:47
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	11 Mar 2021 17:05:26

US3012329

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:53:26

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:05:11
User signature succeeded.	Laurence Chu (b) (4)	12 Mar 2021 19:42:47
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	11 Mar 2021 17:05:26

US3012329

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:53:26

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:05:11
User signature succeeded.	Laurence Chu (b) (4)	12 Mar 2021 19:42:47
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	11 Mar 2021 17:05:26

US3012329

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:53:26

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:05:11
User signature succeeded.	Laurence Chu (b) (4)	12 Mar 2021 19:42:47
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	11 Mar 2021 17:05:26

US3012329

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:53:26

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:05:11
User signature succeeded.	Laurence Chu (b) (4)	12 Mar 2021 19:42:47
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	11 Mar 2021 17:05:26

US3012329

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:53:26

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:05:11
User signature succeeded.	Laurence Chu (b) (4)	12 Mar 2021 19:42:47
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	11 Mar 2021 17:05:26

US3012329

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:53:26

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:05:11
User signature succeeded.	Laurence Chu (b) (4)	12 Mar 2021 19:42:47
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	11 Mar 2021 17:05:26

US3012329

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:53:26

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:05:11
User signature succeeded.	Laurence Chu (b) (4)	12 Mar 2021 19:42:47
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	11 Mar 2021 17:05:26

US3012329

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:53:26

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:05:11
User signature succeeded.	Laurence Chu (b) (4)	12 Mar 2021 19:42:47
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	11 Mar 2021 17:05:26

US3012329

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:53:26

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:05:11
User signature succeeded.	Laurence Chu (b) (4)	12 Mar 2021 19:42:47
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	11 Mar 2021 17:05:26

US3012329

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:53:26

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:05:11
User signature succeeded.	Laurence Chu (b) (4)	12 Mar 2021 19:42:47
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	11 Mar 2021 17:05:26

US3012329

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:53:26

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:05:11
User signature succeeded.	Laurence Chu (b) (4)	12 Mar 2021 19:42:47
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	11 Mar 2021 17:05:26

US3012329

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:53:26

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:05:11
User signature succeeded.	Laurence Chu (b) (4)	12 Mar 2021 19:42:47
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	11 Mar 2021 17:05:26

US3012329

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:53:26

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:05:11
User signature succeeded.	Laurence Chu (b) (4)	12 Mar 2021 19:42:47
	(b) (4)	
User entered 'None (NONE)'	(b) (4), (b) (6)	11 Mar 2021 17:05:26

US3012329

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:53:26

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:05:11
User signature succeeded.	Laurence Chu (b) (4)	12 Mar 2021 19:42:47
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	11 Mar 2021 17:05:26

US3012329

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:53:26

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:05:11
User signature succeeded.	Laurence Chu (b) (4)	12 Mar 2021 19:42:47
	(b) (4)	
User entered 'I'	(b) (4), (b) (6)	11 Mar 2021 17:05:26

US3012329

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:53:26

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:05:11
User signature succeeded.	Laurence Chu (b) (4)	12 Mar 2021 19:42:47
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	11 Mar 2021 17:05:26

US3012329

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:53:26

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:05:11
User signature succeeded.	Laurence Chu (b) (4)	12 Mar 2021 19:42:47
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	11 Mar 2021 17:05:26

US3012329

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:53:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:05:11
User signature succeeded.	Laurence Chu (b) (4)	12 Mar 2021 19:42:47
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	11 Mar 2021 17:05:26

US3012329

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:53:26

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:05:11
User signature succeeded.	Laurence Chu (b) (4)	12 Mar 2021 19:42:47
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	11 Mar 2021 17:05:26

US3012329

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:53:26

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:05:11
User entered '0'	System	11 Mar 2021 17:05:26

US3012329

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:53:26

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:05:11
User entered '0'	System	11 Mar 2021 17:05:26

US3012329

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:53:26

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:05:11

US3012329

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 21:53:26

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	30 Apr 2021 15:32:10
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Papilloma viral infections, PT: Papilloma viral infection, LLT: Human papilloma virus infection - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	29 Apr 2021 23:39:08
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Apr 2021 23:39:08
Data point term sent to Coder	System	29 Apr 2021 23:38:10
User entered 'HPV'	Dean Skiles (b) (4)	29 Apr 2021 23:37:25
	(b) (4)	

US3012329

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 21:53:26

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	30 Apr 2021 15:32:10
User entered 'Yes (Y)'	(b) (4) Dean Skiles (b) (4) (b) (4)	29 Apr 2021 23:37:25

US3012329

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 21:53:26

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	30 Apr 2021 15:32:10
User entered 'No (N)'	(b) (4) Dean Skiles (b) (4) (b) (4)	29 Apr 2021 23:37:25

US3012329

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 21:53:26

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	30 Apr 2021 15:32:10
User entered 'No (N)'	(b) (4) Dean Skiles (b) (4) (b) (4)	29 Apr 2021 23:37:25

US3012329

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 21:53:26

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

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	30 Apr 2021 15:32:10
User entered '21 Mar 2021'	(b) (4) Dean Skiles (b) (4) (b) (4)	29 Apr 2021 23:37:25

US3012329

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 21:53:26

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	30 Apr 2021 15:32:10
User entered empty.	(b) (4) Dean Skiles (b) (4) (b) (4)	29 Apr 2021 23:37:25

US3012329

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 21:53:26

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Apr 2021 23:37:25

US3012329

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 21:53:26

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	30 Apr 2021 15:32:10
User entered 'Yes (Y)'	(b) (4) Dean Skiles (b) (4) (b) (4)	29 Apr 2021 23:37:25

US3012329

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 21:53:26

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	30 Apr 2021 15:32:10
User entered empty.	(b) (4) Dean Skiles (b) (4) (b) (4)	29 Apr 2021 23:37:25

US3012329

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 21:53:26

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	30 Apr 2021 15:32:10
User entered empty.	(b) (4) Dean Skiles (b) (4) (b) (4)	29 Apr 2021 23:37:25

US3012329

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 21:53:26

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Apr 2021 23:37:25

US3012329

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 21:53:26

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	30 Apr 2021 15:32:10
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Dean Skiles (b) (4) (b) (4)	29 Apr 2021 23:37:25

US3012329

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 21:53:26

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	30 Apr 2021 15:32:10
User entered 'No (N)'	(b) (4) Dean Skiles (b) (4) (b) (4)	29 Apr 2021 23:37:25

US3012329

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 21:53:26

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	30 Apr 2021 15:32:10
User entered '0'	(b) (4) Dean Skiles (b) (4) (b) (4)	29 Apr 2021 23:37:25

US3012329

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 21:53:26

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	30 Apr 2021 15:32:10
User entered '0'	(b) (4) Dean Skiles (b) (4) (b) (4)	29 Apr 2021 23:37:25

US3012329

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 21:53:26

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	30 Apr 2021 15:32:10
User entered '0'	(b) (4) Dean Skiles (b) (4) (b) (4)	29 Apr 2021 23:37:25

US3012329

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 21:53:26

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	30 Apr 2021 15:32:10
User entered empty.	(b) (4) Dean Skiles (b) (4) (b) (4)	29 Apr 2021 23:37:25

US3012329

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 21:53:26

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	30 Apr 2021 15:32:10
User entered empty.	(b) (4) Dean Skiles (b) (4) (b) (4)	29 Apr 2021 23:37:25

US3012329

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 21:53:26

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	30 Apr 2021 15:32:10
User entered empty.	(b) (4) Dean Skiles (b) (4) (b) (4)	29 Apr 2021 23:37:25

US3012329

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 21:53:26

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	30 Apr 2021 15:32:10
User entered empty.	(b) (4) Dean Skiles (b) (4) (b) (4)	29 Apr 2021 23:37:25

US3012329

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 21:53:26

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	30 Apr 2021 15:32:10
User entered '0'	(b) (4) Dean Skiles (b) (4) (b) (4)	29 Apr 2021 23:37:25

US3012329

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 21:53:26

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	30 Apr 2021 15:32:10
User entered '0'	(b) (4) Dean Skiles (b) (4) (b) (4)	29 Apr 2021 23:37:25

US3012329

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 21:53:26

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	30 Apr 2021 15:32:10
User entered '0'	(b) (4) Dean Skiles (b) (4) (b) (4)	29 Apr 2021 23:37:25

US3012329

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 21:53:26

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	30 Apr 2021 15:32:10
User entered 'Not Related (NOT RELATED)'	(b) (4) Dean Skiles (b) (4) (b) (4)	29 Apr 2021 23:37:25

US3012329

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 21:53:26

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	30 Apr 2021 15:32:10
User entered 'Not Related (NOT RELATED)'	(b) (4) Dean Skiles (b) (4) (b) (4)	29 Apr 2021 23:37:25

US3012329

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 21:53:26

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	30 Apr 2021 15:32:10
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Dean Skiles (b) (4) (b) (4)	29 Apr 2021 23:37:25

US3012329

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 21:53:26

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	30 Apr 2021 15:32:10
User entered 'I'	(b) (4) Dean Skiles (b) (4) (b) (4)	29 Apr 2021 23:37:25

US3012329

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 21:53:26

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	30 Apr 2021 15:32:10
User entered '0'	(b) (4) Dean Skiles (b) (4) (b) (4)	29 Apr 2021 23:37:25

US3012329

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 21:53:26

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	30 Apr 2021 15:32:10
User entered '0'	(b) (4) Dean Skiles (b) (4) (b) (4)	29 Apr 2021 23:37:25

US3012329

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 21:53:26

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	30 Apr 2021 15:32:10
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4) Dean Skiles (b) (4) (b) (4)	29 Apr 2021 23:37:25

US3012329

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 21:53:26

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	30 Apr 2021 15:32:10
User entered empty.	(b) (4) Dean Skiles (b) (4) (b) (4)	29 Apr 2021 23:37:25

US3012329

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 21:53:26

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	30 Apr 2021 15:32:10
User entered empty.	(b) (4) Dean Skiles (b) (4) (b) (4)	29 Apr 2021 23:37:25

US3012329

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 21:53:26

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	29 Apr 2021 23:37:25

US3012329

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 21:53:26

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	29 Apr 2021 23:37:25

US3012329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 11 Aug 2021 21:53:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:04:01
User closed query 'Per source, subject reported taking Advil (Ibuprofen) starting 11Jan2021. Please verify and add to EDC ConMed Log.' (Site from CRA).		16 Apr 2021 18:47:57
Query 'Per source, subject reported taking Advil (Ibuprofen) starting 11Jan2021. Please verify and add to EDC ConMed Log.' answered with 'ConMed Entered' (Site from CRA).	Jennifer Leyva (b) (4)	16 Apr 2021 17:49:33
User opened query 'Per source, subject reported taking Advil (Ibuprofen) starting 11Jan2021. Please verify and add to EDC ConMed Log.' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 16:32:13
DataPoint Verified.		16 Apr 2021 01:35:14
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered 'Yes (Y)' reason for change: New Information	(b) (4)	
	Jennifer Leyva (b) (4)	20 Jan 2021 00:27:35
	(b) (4)	
User entered 'No (N)'	Jennifer Leyva (b) (4)	17 Sep 2020 21:43:49
	(b) (4)	

US3012329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:53:26

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:08:25
DataPoint Verified.		16 Apr 2021 16:23:39
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
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.	(b) (4)	
	Coder Import (b) (4)	20 Jan 2021 08:34:02
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	20 Jan 2021 08:34:02
	(b) (4)	
Data point term sent to Coder	System	20 Jan 2021 00:31:21
User entered 'zithromax'	Jennifer Leyva (b) (4)	20 Jan 2021 00:30:23
	(b) (4)	

US3012329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:53:26

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:08:25
DataPoint Verified.		16 Apr 2021 16:23:41
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered 'No (N)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	20 Jan 2021 00:30:23

US3012329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:53:26

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:08:25
DataPoint Verified.		16 Apr 2021 16:23:43
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered 'Covid-19 Infection (AE #1)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	20 Jan 2021 00:30:23

US3012329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:53:26

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:08:25
DataPoint Verified.		16 Apr 2021 16:23:45
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered '250'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	20 Jan 2021 00:30:23

US3012329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:53:26

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:08:25
DataPoint Verified.		16 Apr 2021 16:23:47
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered 'mg (mg)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	20 Jan 2021 00:30:23

US3012329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:53:26

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:08:25
DataPoint Verified.		16 Apr 2021 16:23:49
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered empty.	(b) (4) Jennifer Leyva (b) (4) (b) (4)	20 Jan 2021 00:30:23

US3012329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:53:26

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:08:25
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:23:51
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered 'once daily (QD)'	Jennifer Leyva (b) (4)	20 Jan 2021 00:30:23

US3012329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:53:26

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:08:25
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:23:52
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered empty.	Jennifer Leyva (b) (4)	20 Jan 2021 00:30:23

US3012329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:53:26

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:08:25
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:23:54
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered 'Oral (ORAL)'	Jennifer Leyva (b) (4)	20 Jan 2021 00:30:23

US3012329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:53:26

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:08:25
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:23:55
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered empty.	Jennifer Leyva (b) (4)	20 Jan 2021 00:30:23

US3012329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:53:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:08:25
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:23:57
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered '19 Jan 2021'	Jennifer Leyva (b) (4)	20 Jan 2021 00:30:23

US3012329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:53:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:08:25
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:23:59
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered '0'	Jennifer Leyva (b) (4)	20 Jan 2021 00:30:23

US3012329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:53:26

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:08:25
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:24:01
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User closed query 'Per DM CLR: Please note, the corresponding AE has resolved. However, this medication is still ongoing. Please reconcile AE/CM dates and update as appropriate. Otherwise, clarify continued use after AE resolution.' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Mar 2021 11:21:48
Query 'Per DM CLR: Please note, the corresponding AE has resolved. However, this medication is still ongoing. Please reconcile AE/CM dates and update as appropriate. Otherwise, clarify continued use after AE resolution.' answered with 'updated' (Site from DM).	Pamela Fidler (b) (4)	19 Mar 2021 20:46:29
User entered 'No (N)' reason for change: Data Entry Error	Pamela Fidler (b) (4)	19 Mar 2021 20:46:03
User opened query 'Per DM CLR: Please note, the corresponding AE has resolved. However, this medication is still ongoing. Please reconcile AE/CM dates and update as appropriate. Otherwise, clarify continued use after AE resolution.' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 18:36:23
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	20 Jan 2021 00:30:23

US3012329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:53:26

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:08:25
DataPoint Verified.		16 Apr 2021 18:44:57
User closed query 'Per source, end date for ConMed is recorded as, 06Feb2021. Please verify and update EDC accordingly.' (Site from CRA).		16 Apr 2021 18:44:55
User signature succeeded.	Laurence Chu (b) (4)	16 Apr 2021 18:18:05
Query 'Per source, end date for ConMed is recorded as, 06Feb2021. Please verify and update EDC accordingly.' answered with 'Updated' (Site from CRA).	(b) (4) Jennifer Leyva (b) (4)	16 Apr 2021 17:37:41
Signature has been broken.	(b) (4) Jennifer Leyva (b) (4)	16 Apr 2021 17:37:27
User entered '06 Feb 2021' reason for change: Data Entry Error	Jennifer Leyva (b) (4)	16 Apr 2021 17:37:27
User opened query 'Per source, end date for ConMed is recorded as, 06Feb2021. Please verify and update EDC accordingly.' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 16:24:37
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered '25 Jan 2021' reason for change: Data Entry Error	(b) (4) Pamela Fidler (b) (4)	19 Mar 2021 20:46:03
User entered empty.	Jennifer Leyva (b) (4)	20 Jan 2021 00:30:23

US3012329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:53:26

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:08:25
DataPoint Verified.		16 Apr 2021 16:24:41
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered 'No (N)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	20 Jan 2021 00:30:23

US3012329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:53:26

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:08:25
User entered '1'	System	20 Jan 2021 00:30:23

US3012329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:53:26

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:08:25
User entered '1'	System	20 Jan 2021 00:30:23

US3012329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:53:26

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:08:25
User entered '804 (804)'	System	20 Jan 2021 00:30:23

US3012329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:53:26

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:09:16
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:24:53
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
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.	(b) (4) Coder Import (b) (4) (b) (4)	20 Jan 2021 00:32:12
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Jan 2021 00:32:12
Data point term sent to Coder	System	20 Jan 2021 00:31:21
User entered 'Tylenol'	Jennifer Leyva (b) (4) (b) (4)	20 Jan 2021 00:30:53

US3012329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:53:26

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:09:16
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:24:57
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered 'No (N)'	Jennifer Leyva (b) (4)	20 Jan 2021 00:30:53

US3012329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:53:26

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:09:16
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:24:58
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered 'COVID-19 Infection (AE #1)'	Jennifer Leyva (b) (4)	20 Jan 2021 00:30:53

US3012329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:53:26

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:09:16
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:25:00
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered '1000'	Jennifer Leyva (b) (4)	20 Jan 2021 00:30:53

US3012329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:53:26

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:09:16
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:25:02
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered 'mg (mg)'	Jennifer Leyva (b) (4)	20 Jan 2021 00:30:53

US3012329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:53:26

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:09:16
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:25:04
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered empty.	Jennifer Leyva (b) (4)	20 Jan 2021 00:30:53

US3012329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:53:26

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:09:16
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:25:06
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered 'as needed (PRN)'	Jennifer Leyva (b) (4)	20 Jan 2021 00:30:53

US3012329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:53:26

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:09:16
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:25:07
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered empty.	Jennifer Leyva (b) (4)	20 Jan 2021 00:30:53

US3012329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:53:26

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:09:16
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:25:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered 'Oral (ORAL)'	Jennifer Leyva (b) (4)	20 Jan 2021 00:30:53

US3012329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:53:26

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:09:16
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:25:11
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered empty.	Jennifer Leyva (b) (4)	20 Jan 2021 00:30:53

US3012329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:53:26

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:09:16
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:25:13
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered '19 Jan 2021'	Jennifer Leyva (b) (4)	20 Jan 2021 00:30:53

US3012329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:53:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:09:16
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:25:15
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered '0'	Jennifer Leyva (b) (4)	20 Jan 2021 00:30:53

US3012329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:53:26

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:09:16
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:25:17
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User closed query 'Per DM CLR: Please note, the corresponding AE has resolved. However, this medication is still ongoing. Please reconcile AE/CM dates and update as appropriate. Otherwise, clarify continued use after AE resolution.' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Mar 2021 11:22:00
Query 'Per DM CLR: Please note, the corresponding AE has resolved. However, this medication is still ongoing. Please reconcile AE/CM dates and update as appropriate. Otherwise, clarify continued use after AE resolution.' answered with 'updated' (Site from DM).	Pamela Fidler (b) (4)	19 Mar 2021 20:46:20
User entered 'No (N)' reason for change: Data Entry Error	Pamela Fidler (b) (4)	19 Mar 2021 20:46:14
User opened query 'Per DM CLR: Please note, the corresponding AE has resolved. However, this medication is still ongoing. Please reconcile AE/CM dates and update as appropriate. Otherwise, clarify continued use after AE resolution.' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 18:36:36
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	20 Jan 2021 00:30:53

US3012329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:53:26

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:09:16
DataPoint Verified.		16 Apr 2021 18:45:13
User closed query 'Per source, end date of ConMed is recorded as, 06Feb2021. Please verify and update EDC accordingly.' (Site from CRA).		16 Apr 2021 18:45:11
User signature succeeded.	Laurence Chu (b) (4)	16 Apr 2021 18:18:05
Query 'Per source, end date of ConMed is recorded as, 06Feb2021. Please verify and update EDC accordingly.' answered with 'Updated' (Site from CRA).	(b) (4) Jennifer Leyva (b) (4)	16 Apr 2021 17:38:35
Signature has been broken.	(b) (4) Jennifer Leyva (b) (4)	16 Apr 2021 17:38:16
User entered '06 Feb 2021' reason for change: Data Entry Error	Jennifer Leyva (b) (4)	16 Apr 2021 17:38:16
User opened query 'Per source, end date of ConMed is recorded as, 06Feb2021. Please verify and update EDC accordingly.' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 16:25:38
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered '25 Jan 2021' reason for change: Data Entry Error	(b) (4) Pamela Fidler (b) (4)	19 Mar 2021 20:46:14
User entered empty.	Jennifer Leyva (b) (4)	20 Jan 2021 00:30:53

US3012329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:53:26

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:09:16
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:25:40
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered 'No (N)'	Jennifer Leyva (b) (4)	20 Jan 2021 00:30:53

US3012329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:53:26

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:09:16
User entered empty.	System	20 Jan 2021 00:30:53

US3012329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:53:26

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:09:16
User entered empty.	System	20 Jan 2021 00:30:53

US3012329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:53:26

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:09:16
User entered empty.	System	20 Jan 2021 00:30:53

US3012329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:53:26

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:08:54
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:25:56
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOIDS, PRODUCT: PREDNISONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Jan 2021 08:16:59
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Jan 2021 08:16:59
Data point term sent to Coder	System	20 Jan 2021 00:31:22
User entered 'Prednisone'	Jennifer Leyva (b) (4)	20 Jan 2021 00:31:18

US3012329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:53:26

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:08:54
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:26:01
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered 'No (N)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	20 Jan 2021 00:31:18

US3012329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:53:26

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:08:54
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:26:04
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered 'COVID-19 Infection (AE #1)'	Jennifer Leyva (b) (4)	20 Jan 2021 00:31:18

US3012329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:53:26

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:08:54
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:26:06
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered '80'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	20 Jan 2021 00:31:18

US3012329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:53:26

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:08:54
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:26:08
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered 'mg (mg)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	20 Jan 2021 00:31:18

US3012329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:53:26

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:08:54
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:26:11
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered empty.	(b) (4) Jennifer Leyva (b) (4) (b) (4)	20 Jan 2021 00:31:18

US3012329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:53:26

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:08:54
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:43:41
User signature succeeded.	Laurence Chu (b) (4)	16 Apr 2021 18:18:05
User closed query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	(b) (4)	16 Apr 2021 17:40:33
Query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' answered by data change (Site from System).	System	16 Apr 2021 17:40:33
DataPoint Un-verified.	Jennifer Leyva (b) (4)	16 Apr 2021 17:40:33
Signature has been broken.	(b) (4)	16 Apr 2021 17:40:33
User entered 'once daily (QD)' reason for change: Data Entry Error	Jennifer Leyva (b) (4)	16 Apr 2021 17:40:33
User opened query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	(b) (4)	16 Apr 2021 17:39:32
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:26:13
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered 'once (ONCE)'	(b) (4)	20 Jan 2021 00:31:18
	Jennifer Leyva (b) (4)	
	(b) (4)	

US3012329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:53:26

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:08:54
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:26:16
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered empty.	(b) (4) Jennifer Leyva (b) (4) (b) (4)	20 Jan 2021 00:31:18

US3012329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:53:26

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:08:54
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:26:17
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered 'Oral (ORAL)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	20 Jan 2021 00:31:18

US3012329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:53:26

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:08:54
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:26:19
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered empty.	Jennifer Leyva (b) (4)	20 Jan 2021 00:31:18

US3012329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:53:26

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:08:54
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:26:21
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered '19 Jan 2021'	Jennifer Leyva (b) (4)	20 Jan 2021 00:31:18

US3012329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:53:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:08:54
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:26:22
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered '0'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	20 Jan 2021 00:31:18

US3012329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:53:26

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:08:54
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:26:24
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered 'No (N)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	20 Jan 2021 00:31:18

US3012329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:53:26

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:08:54
DataPoint Verified.		16 Apr 2021 18:46:18
User closed query 'Per source, end date of ConMed is recorded as, 24Jan2021. Please verify and update EDC accordingly.' (Site from CRA).		16 Apr 2021 18:46:16
User signature succeeded.	Laurence Chu (b) (4)	16 Apr 2021 18:18:05
Query 'Per source, end date of ConMed is recorded as, 24Jan2021. Please verify and update EDC accordingly.' answered with 'Already recorded as 24Jan2021' (Site from CRA).	(b) (4)	
Signature has been broken.	Jennifer Leyva (b) (4)	16 Apr 2021 17:40:59
	(b) (4)	
Signature has been broken.	Jennifer Leyva (b) (4)	16 Apr 2021 17:39:32
User entered '24 Jan 2021' reason for change: Data Entry Error	(b) (4)	
User opened query 'Per source, end date of ConMed is recorded as, 24Jan2021. Please verify and update EDC accordingly.' (Site from CRA).	Jennifer Leyva (b) (4)	16 Apr 2021 17:39:32
User signature succeeded.	(b) (4)	
User entered '19 Jan 2021'	(b) (4), (b) (6)	16 Apr 2021 16:26:54
	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
	(b) (4)	
	Jennifer Leyva (b) (4)	20 Jan 2021 00:31:18
	(b) (4)	

US3012329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:53:26

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:08:54
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:26:28
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered 'No (N)'	Jennifer Leyva (b) (4)	20 Jan 2021 00:31:18

US3012329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:53:26

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:08:54
User entered '1'	System	16 Apr 2021 17:40:33
User entered empty.	System	20 Jan 2021 00:31:18

US3012329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:53:26

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:08:54
User entered '1'	System	16 Apr 2021 17:40:33
User entered empty.	System	20 Jan 2021 00:31:18

US3012329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:53:26

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:08:54
User entered '804 (804)'	System	16 Apr 2021 17:40:33
User entered empty.	System	20 Jan 2021 00:31:18

US3012329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:53:26

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:06:48
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:27:00
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
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: IBUPROFEN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	28 Jan 2021 01:08:09
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Jan 2021 01:08:09
Data point term sent to Coder	System	27 Jan 2021 21:00:38
User entered 'Ibuprofen'	Jennifer Leyva (b) (4) (b) (4)	27 Jan 2021 21:00:10

US3012329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:53:26

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:06:48
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:27:03
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered 'No (N)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Jan 2021 21:00:10

US3012329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:53:26

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:06:48
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:27:04
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered 'COVID-19 Infection (AE #2)'	Jennifer Leyva (b) (4)	27 Jan 2021 21:00:10

US3012329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:53:26

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:06:48
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:27:06
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered '400'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Jan 2021 21:00:10

US3012329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:53:26

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:06:48
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:27:08
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered 'mg (mg)'	Jennifer Leyva (b) (4)	27 Jan 2021 21:00:10

US3012329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:53:26

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:06:48
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:27:10
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered empty.	Jennifer Leyva (b) (4)	27 Jan 2021 21:00:10

US3012329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:53:26

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:06:48
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:27:11
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered 'as needed (PRN)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Jan 2021 21:00:10

US3012329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:53:26

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:06:48
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:27:13
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered empty.	Jennifer Leyva (b) (4)	27 Jan 2021 21:00:10

US3012329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:53:26

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:06:48
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:27:15
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered 'Oral (ORAL)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Jan 2021 21:00:10

US3012329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:53:26

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:06:48
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:27:17
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered empty.	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Jan 2021 21:00:10

US3012329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:53:26

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:06:48
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:27:20
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered '25 Jan 2021'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Jan 2021 21:00:10

US3012329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:53:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:06:48
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:27:22
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered '0'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Jan 2021 21:00:10

US3012329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:53:26

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:06:48
DataPoint Verified.		16 Apr 2021 18:47:27
User closed query 'Per source, end date for ConMed is recorded as, 06Feb2021. Please verify with source and update EDC accordingly.' (Site from CRA).		16 Apr 2021 18:47:23
User signature succeeded.	Laurence Chu (b) (4)	16 Apr 2021 18:18:05
Query 'Per source, end date for ConMed is recorded as, 06Feb2021. Please verify with source and update EDC accordingly.' answered with 'Updated' (Site from CRA).	(b) (4) Jennifer Leyva (b) (4)	16 Apr 2021 17:42:14
Signature has been broken.	(b) (4) Jennifer Leyva (b) (4)	16 Apr 2021 17:41:51
User entered 'No (N)' reason for change: New Information	Jennifer Leyva (b) (4)	16 Apr 2021 17:41:51
User opened query 'Per source, end date for ConMed is recorded as, 06Feb2021. Please verify with source and update EDC accordingly.' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 16:27:49
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User closed query 'Per DM CLR: Please note, the corresponding AE has resolved. However, this medication is still ongoing. Please reconcile AE/CM dates and update as appropriate. Otherwise, clarify continued use after AE resolution.' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Mar 2021 11:22:34
Query 'Per DM CLR: Please note, the corresponding AE has resolved. However, this medication is still ongoing. Please reconcile AE/CM dates and update as appropriate. Otherwise, clarify continued use after AE resolution.' answered with 'ongoing' (Site from DM).	Pamela Fidler (b) (4)	19 Mar 2021 20:46:46
User opened query 'Per DM CLR: Please note, the corresponding AE has resolved. However, this medication is still ongoing. Please reconcile AE/CM dates and update as appropriate. Otherwise, clarify continued use after AE resolution.' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 18:36:55
User entered 'Yes (Y)'	Jennifer Leyva (b) (4)	27 Jan 2021 21:00:10

US3012329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:53:26

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:06:48
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:47:25
User signature succeeded.	Laurence Chu (b) (4)	16 Apr 2021 18:18:05
DataPoint Un-verified.	(b) (4)	
	Jennifer Leyva (b) (4)	16 Apr 2021 17:41:51
Signature has been broken.	(b) (4)	
	Jennifer Leyva (b) (4)	16 Apr 2021 17:41:51
User entered '06 Feb 2021' reason for change: New Information	(b) (4)	16 Apr 2021 17:41:51
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:27:52
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered empty.	(b) (4)	
	Jennifer Leyva (b) (4)	27 Jan 2021 21:00:10
	(b) (4)	

US3012329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:53:26

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:06:48
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:27:55
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered 'No (N)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Jan 2021 21:00:10

US3012329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:53:26

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:06:48
User entered empty.	System	27 Jan 2021 21:00:10

US3012329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:53:26

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:06:48
User entered empty.	System	27 Jan 2021 21:00:10

US3012329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:53:26

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:06:48
User entered empty.	System	27 Jan 2021 21:00:10

US3012329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:53:26

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:33:05
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:28:01
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: DEXAMETHASONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	28 Jan 2021 00:45:10
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	28 Jan 2021 00:45:10
Data point term sent to Coder	System	27 Jan 2021 21:01:38
User entered 'Dexamethasone'	Jennifer Leyva (b) (4)	27 Jan 2021 21:00:40

US3012329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:53:26

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:33:05
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:28:04
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered 'No (N)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Jan 2021 21:00:40

US3012329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:53:26

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:33:05
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:28:05
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered 'COVID-19 Infection (AE #2)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Jan 2021 21:00:40

US3012329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:53:26

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:33:05
DataPoint Verified.		16 Apr 2021 16:28:07
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM).		01 Apr 2021 10:28:43
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' answered with 'This is as reported by the patient ' (Site from DM).	Pamela Fidler (b) (4)	29 Mar 2021 17:11:31
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 09:19:31
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered '200'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Jan 2021 21:00:40

US3012329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:53:26

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:33:05
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:28:10
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered 'mg (mg)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Jan 2021 21:00:40

US3012329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:53:26

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:33:05
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:28:12
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered empty.	Jennifer Leyva (b) (4)	27 Jan 2021 21:00:40

US3012329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:53:26

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:33:05
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:28:15
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered 'as needed (PRN)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Jan 2021 21:00:40

US3012329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:53:26

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:33:05
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:28:16
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered empty.	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Jan 2021 21:00:40

US3012329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:53:26

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:33:05
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:28:21
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered 'Oral (ORAL)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Jan 2021 21:00:40

US3012329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:53:26

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:33:05
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:28:23
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered empty.	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Jan 2021 21:00:40

US3012329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:53:26

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:33:05
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:28:24
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered '25 Jan 2021'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Jan 2021 21:00:40

US3012329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:53:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:33:05
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:28:26
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered '0'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Jan 2021 21:00:40

US3012329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:53:26

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:33:05
DataPoint Verified.		16 Apr 2021 16:28:32
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User closed query 'Per DM CLR: Please note, the corresponding AE has resolved. However, this medication is still ongoing. Please reconcile AE/CM dates and update as appropriate. Otherwise, clarify continued use after AE resolution.' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Mar 2021 11:23:18
Query 'Per DM CLR: Please note, the corresponding AE has resolved. However, this medication is still ongoing. Please reconcile AE/CM dates and update as appropriate. Otherwise, clarify continued use after AE resolution.' answered with 'updated' (Site from DM).	Pamela Fidler (b) (4)	19 Mar 2021 20:47:19
User entered 'No (N)' reason for change: Data Entry Error	Pamela Fidler (b) (4)	19 Mar 2021 20:47:12
User opened query 'Per DM CLR: Please note, the corresponding AE has resolved. However, this medication is still ongoing. Please reconcile AE/CM dates and update as appropriate. Otherwise, clarify continued use after AE resolution.' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 18:37:11
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	27 Jan 2021 21:00:40

US3012329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:53:26

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:33:05
DataPoint Verified.		16 Apr 2021 18:47:35
User closed query 'Per source, end date for ConMed is recorded as, 06Feb2021. Please verify with source and update EDC accordingly.' (Site from CRA).		16 Apr 2021 18:47:34
User signature succeeded.	Laurence Chu (b) (4)	16 Apr 2021 18:18:05
Query 'Per source, end date for ConMed is recorded as, 06Feb2021. Please verify with source and update EDC accordingly.' answered with 'Updated' (Site from CRA).	(b) (4) Jennifer Leyva (b) (4)	16 Apr 2021 17:43:09
Signature has been broken.	(b) (4) Jennifer Leyva (b) (4)	16 Apr 2021 17:42:48
User entered '06 Feb 2021' reason for change: Data Entry Error	Jennifer Leyva (b) (4)	16 Apr 2021 17:42:48
User opened query 'Per source, end date for ConMed is recorded as, 06Feb2021. Please verify with source and update EDC accordingly.' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 16:28:42
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered '25 Jan 2021' reason for change: Data Entry Error	(b) (4) Pamela Fidler (b) (4)	19 Mar 2021 20:47:12
User entered empty.	Jennifer Leyva (b) (4)	27 Jan 2021 21:00:40

US3012329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:53:26

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:33:05
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:28:34
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered 'No (N)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Jan 2021 21:00:40

US3012329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:53:26

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:33:05
User entered empty.	System	27 Jan 2021 21:00:40

US3012329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:53:26

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:33:05
User entered empty.	System	27 Jan 2021 21:00:40

US3012329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:53:26

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:33:05
User entered empty.	System	27 Jan 2021 21:00:40

US3012329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:53:26

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:33:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:29:11
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: COUGH SUPPRESSANTS, EXCL. COMBINATIONS WITH EXPECTORANTS, ATC: OTHER COUGH SUPPRESSANTS, PRODUCT: BENZONATATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Jan 2021 00:39:09
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Jan 2021 00:39:09
Data point term sent to Coder	System	27 Jan 2021 21:01:39
User entered 'Benzenotate'	Jennifer Leyva (b) (4)	27 Jan 2021 21:01:02

US3012329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:53:26

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:33:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:29:13
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered 'No (N)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Jan 2021 21:01:02

US3012329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:53:26

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:33:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:29:15
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered 'COVID-19 Infection (AE #2)'	Jennifer Leyva (b) (4)	27 Jan 2021 21:01:02

US3012329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:53:26

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:33:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:29:17
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered '200'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Jan 2021 21:01:02

US3012329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:53:26

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:33:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:29:20
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered 'mg (mg)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Jan 2021 21:01:02

US3012329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:53:26

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:33:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:29:22
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered empty.	Jennifer Leyva (b) (4)	27 Jan 2021 21:01:02

US3012329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:53:26

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:33:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:29:24
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered 'once daily (QD)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Jan 2021 21:01:02

US3012329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:53:26

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:33:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:29:25
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered empty.	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Jan 2021 21:01:02

US3012329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:53:26

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:33:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:29:27
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered 'Oral (ORAL)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Jan 2021 21:01:02

US3012329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:53:26

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:33:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:29:28
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered empty.	Jennifer Leyva (b) (4)	27 Jan 2021 21:01:02

US3012329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:53:26

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:33:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:29:30
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered '25 Jan 2021'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Jan 2021 21:01:02

US3012329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:53:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:33:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:29:32
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered '0'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Jan 2021 21:01:02

US3012329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:53:26

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:33:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:47:44
User closed query 'Per source, end date for ConMed is recorded as, 06Feb2021. Please verify with source and update EDC accordingly.' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 18:47:42
User signature succeeded.	Laurence Chu (b) (4)	16 Apr 2021 18:18:05
Query 'Per source, end date for ConMed is recorded as, 06Feb2021. Please verify with source and update EDC accordingly.' answered with 'Updated' (Site from CRA).	Jennifer Leyva (b) (4)	16 Apr 2021 17:44:58
Signature has been broken.	Jennifer Leyva (b) (4)	16 Apr 2021 17:44:35
User entered 'No (N)' reason for change: New Information	Jennifer Leyva (b) (4)	16 Apr 2021 17:44:35
User opened query 'Per source, end date for ConMed is recorded as, 06Feb2021. Please verify with source and update EDC accordingly.' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 16:29:40
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User closed query 'Per DM CLR: Please note, the corresponding AE has resolved. However, this medication is still ongoing. Please reconcile AE/CM dates and update as appropriate. Otherwise, clarify continued use after AE resolution.' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 11:23:42
Query 'Per DM CLR: Please note, the corresponding AE has resolved. However, this medication is still ongoing. Please reconcile AE/CM dates and update as appropriate. Otherwise, clarify continued use after AE resolution.' answered with 'ongoing' (Site from DM).	Pamela Fidler (b) (4)	19 Mar 2021 20:47:33
User opened query 'Per DM CLR: Please note, the corresponding AE has resolved. However, this medication is still ongoing. Please reconcile AE/CM dates and update as appropriate. Otherwise, clarify continued use after AE resolution.' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 18:37:49
User entered 'Yes (Y)'	Jennifer Leyva (b) (4)	27 Jan 2021 21:01:02

US3012329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:53:26

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:33:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:47:46
User signature succeeded.	Laurence Chu (b) (4)	16 Apr 2021 18:18:05
Signature has been broken.	(b) (4) Jennifer Leyva (b) (4)	16 Apr 2021 17:44:35
User entered '06 Feb 2021' reason for change: New Information	(b) (4) Jennifer Leyva (b) (4)	16 Apr 2021 17:44:35
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered empty.	(b) (4) Jennifer Leyva (b) (4)	27 Jan 2021 21:01:02

US3012329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:53:26

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:33:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:29:42
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered 'No (N)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	27 Jan 2021 21:01:02

US3012329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:53:26

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:33:02
User entered '1'	System	27 Jan 2021 21:01:02

US3012329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:53:26

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:33:02
User entered '1'	System	27 Jan 2021 21:01:02

US3012329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:53:26

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:33:02
User entered '804 (804)'	System	27 Jan 2021 21:01:02

US3012329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 21:53:26

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:08:38
DataPoint Verified.		16 Apr 2021 16:30:59
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: SULFONAMIDES AND TRIMETHOPRIM, ATC: COMBINATIONS OF SULFONAMIDES AND TRIMETHOPRIM, INCL. DERIVATIVES, PRODUCT: SULFAMETHOXAZOLE;TRIMETHOPRIM, PRODUCTSYNONYM: BACTRIM DS - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	11 Mar 2021 17:39:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Mar 2021 17:39:50
Data point term sent to Coder	System	11 Mar 2021 17:08:00
User entered 'Bactrim DS'	(b) (4), (b) (6)	11 Mar 2021 17:07:16

US3012329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 21:53:26

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:08:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:31:02
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered 'No (N)'	(b) (4), (b) (6)	11 Mar 2021 17:07:16

US3012329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 21:53:26

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:08:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:31:04
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered 'urinary tract infection'	(b) (4), (b) (6)	11 Mar 2021 17:07:16

US3012329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 21:53:26

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:08:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:31:07
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered '160/800'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 17:07:16

US3012329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 21:53:26

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:08:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:31:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered 'mg (mg)'	(b) (4), (b) (6)	11 Mar 2021 17:07:16

US3012329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 21:53:26

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:08:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:31:10
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered empty.	(b) (4), (b) (6)	11 Mar 2021 17:07:16

US3012329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 21:53:26

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:08:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:31:12
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered 'twice daily (BID)'	(b) (4), (b) (6)	11 Mar 2021 17:07:16

US3012329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 21:53:26

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:08:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:31:14
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered empty.	(b) (4), (b) (6)	11 Mar 2021 17:07:16

US3012329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 21:53:26

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:08:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:31:18
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	11 Mar 2021 17:07:16

US3012329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 21:53:26

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:08:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:31:21
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered empty.	(b) (4), (b) (6)	11 Mar 2021 17:07:16

US3012329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 21:53:26

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:08:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:31:25
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered '8 Mar 2021'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 17:07:16

US3012329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 21:53:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:08:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:31:26
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered '0'	(b) (4), (b) (6)	11 Mar 2021 17:07:16

US3012329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 21:53:26

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:08:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:31:28
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered 'No (N)'	(b) (4), (b) (6)	11 Mar 2021 17:07:16

US3012329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 21:53:26

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:08:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:31:31
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered '11 Mar 2021'	(b) (4), (b) (6)	11 Mar 2021 17:07:16

US3012329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 21:53:26

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:08:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:31:34
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered 'No (N)'	(b) (4), (b) (6)	11 Mar 2021 17:07:16

US3012329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 21:53:26

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:08:38
User entered '2'	System	11 Mar 2021 17:07:16

US3012329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 21:53:26

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:08:38
User entered '1'	System	11 Mar 2021 17:07:16

US3012329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 21:53:26

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:08:38
User entered '804 (804)'	System	11 Mar 2021 17:07:16

US3012329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 21:53:26

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:32:57
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: IBUPROFEN, PRODUCTSYNONYM: ADVIL [IBUPROFEN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Apr 2021 07:45:27
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Apr 2021 07:45:27
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:44:06
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	16 Apr 2021 18:18:05
Data point term sent to Coder System	Jennifer Leyva (b) (4) (b) (4)	16 Apr 2021 17:48:51 16 Apr 2021 17:48:38

US3012329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 21:53:26

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:32:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:44:11
User signature succeeded.	Laurence Chu (b) (4)	16 Apr 2021 18:18:05
User entered 'No (N)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	16 Apr 2021 17:48:38

US3012329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 21:53:26

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:32:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:44:14
User signature succeeded.	Laurence Chu (b) (4)	16 Apr 2021 18:18:05
User entered 'Headache, Body aches (due to COVID Infection (AE #1)'	Jennifer Leyva (b) (4)	16 Apr 2021 17:48:38

US3012329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 21:53:26

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:32:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:44:16
User signature succeeded.	Laurence Chu (b) (4)	16 Apr 2021 18:18:05
User entered '400'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	16 Apr 2021 17:48:38

US3012329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 21:53:26

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:32:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:44:17
User signature succeeded.	Laurence Chu (b) (4)	16 Apr 2021 18:18:05
User entered 'mg (mg)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	16 Apr 2021 17:48:38

US3012329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 21:53:26

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:32:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:44:18
User signature succeeded.	Laurence Chu (b) (4)	16 Apr 2021 18:18:05
User entered empty.	(b) (4) Jennifer Leyva (b) (4) (b) (4)	16 Apr 2021 17:48:38

US3012329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 21:53:26

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:32:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:44:20
User signature succeeded.	Laurence Chu (b) (4)	16 Apr 2021 18:18:05
User entered 'as needed (PRN)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	16 Apr 2021 17:48:38

US3012329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 21:53:26

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:32:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:44:22
User signature succeeded.	Laurence Chu (b) (4)	16 Apr 2021 18:18:05
User entered empty.	(b) (4) Jennifer Leyva (b) (4) (b) (4)	16 Apr 2021 17:48:38

US3012329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 21:53:26

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:32:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:44:24
User signature succeeded.	Laurence Chu (b) (4)	16 Apr 2021 18:18:05
User entered 'Oral (ORAL)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	16 Apr 2021 17:48:38

US3012329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 21:53:26

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:32:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:44:26
User signature succeeded.	Laurence Chu (b) (4)	16 Apr 2021 18:18:05
User entered empty.	(b) (4) Jennifer Leyva (b) (4) (b) (4)	16 Apr 2021 17:48:38

US3012329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 21:53:26

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:32:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:44:28
User signature succeeded.	Laurence Chu (b) (4)	16 Apr 2021 18:18:05
User entered '11 Jan 2021'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	16 Apr 2021 17:48:38

US3012329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 21:53:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:32:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:44:30
User signature succeeded.	Laurence Chu (b) (4)	16 Apr 2021 18:18:05
User entered '0'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	16 Apr 2021 17:48:38

US3012329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 21:53:26

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:32:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:44:32
User signature succeeded.	Laurence Chu (b) (4)	16 Apr 2021 18:18:05
User entered 'No (N)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	16 Apr 2021 17:48:38

US3012329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 21:53:26

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:32:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:44:34
User signature succeeded.	Laurence Chu (b) (4)	16 Apr 2021 18:18:05
User entered '12 Jan 2021'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	16 Apr 2021 17:48:38

US3012329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 21:53:26

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:32:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:44:36
User signature succeeded.	Laurence Chu (b) (4)	16 Apr 2021 18:18:05
User entered 'No (N)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	16 Apr 2021 17:48:38

US3012329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 21:53:26

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:32:57
User entered empty.	System	16 Apr 2021 17:48:38

US3012329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 21:53:26

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:32:57
User entered empty.	System	16 Apr 2021 17:48:38

US3012329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 21:53:26

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:32:57
User entered empty.	System	16 Apr 2021 17:48:38

US3012329

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 11 Aug 2021 21:53:26

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 01:35:39
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered 'No (N)'	Jennifer Leyva (b) (4)	17 Sep 2020 21:43:53

US3012329

Folder: SAE USA-US006-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:26

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:29:22
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 13:27:06
User entered 'USA-US006-2021-MRNA-1273-P301000003'	System	20 Jan 2021 13:26:52

US3012329

Folder: SAE USA-US006-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:26

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:29:22
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:29:16
Un-reviewed for Safety.	System	03 Feb 2021 22:28:03
User entered 'No (N)'	System	03 Feb 2021 22:28:03
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 21:35:43
User entered 'Yes (Y)'	System	28 Jan 2021 20:11:03
User entered 'No (N)'	System	27 Jan 2021 20:08:04
Un-reviewed for Safety.	System	27 Jan 2021 18:01:47
User entered 'Yes (Y)'	System	27 Jan 2021 18:01:47
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 13:27:06
User entered 'No (N)'	System	20 Jan 2021 13:26:52

US3012329

Folder: SAE USA-US006-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:26

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:29:22
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 13:27:06
User entered 'No (N)'	System	20 Jan 2021 13:26:52

US3012329

Folder: SAE USA-US006-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:26

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:29:22
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 13:27:06
User entered 'No (N)'	System	20 Jan 2021 13:26:52

US3012329

Folder: SAE USA-US006-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:26

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:29:22
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	12 Feb 2021 17:29:12
Un-reviewed for Safety.	System	03 Feb 2021 22:28:03
User entered 'No (N)'	System	03 Feb 2021 22:28:03
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 21:35:43
User entered 'Yes (Y)'	System	28 Jan 2021 20:11:03
User entered 'No (N)'	System	27 Jan 2021 20:08:04
Un-reviewed for Safety.	System	27 Jan 2021 18:01:47
User entered 'Yes (Y)'	System	27 Jan 2021 18:01:47
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 13:27:06
User entered 'No (N)'	System	20 Jan 2021 13:26:52

US3012329

Folder: SAE USA-US006-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:26

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:29:22
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 13:27:06
User entered 'No (N)'	System	20 Jan 2021 13:26:52

US3012329

Folder: SAE USA-US006-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:26

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:29:22
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 13:27:06
User entered 'No (N)'	System	20 Jan 2021 13:26:52

US3012329

Folder: SAE USA-US006-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:26

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:29:22
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 13:27:06
User entered 'No (N)'	System	20 Jan 2021 13:26:52

US3012329

Folder: SAE USA-US006-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:26

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:29:22
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 13:27:06
User entered 'Laurence'	System	20 Jan 2021 13:26:52

US3012329

Folder: SAE USA-US006-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:26

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:29:22
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 13:27:06
User entered 'Chu'	System	20 Jan 2021 13:26:52

US3012329

Folder: SAE USA-US006-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:26

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:29:22
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 13:27:06
User entered '3100 Red River Street'	System	20 Jan 2021 13:26:52

US3012329

Folder: SAE USA-US006-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:26

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:29:22
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 13:27:06
User entered 'Austin'	System	20 Jan 2021 13:26:52

US3012329

Folder: SAE USA-US006-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:26

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:29:22
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 13:27:06
User entered 'TX'	System	20 Jan 2021 13:26:52

US3012329

Folder: SAE USA-US006-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:26

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:29:22
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 13:27:06
User entered '78705'	System	20 Jan 2021 13:26:52

US3012329

Folder: SAE USA-US006-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:26

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:29:22
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 21:35:43
User entered 'US'	System	20 Jan 2021 13:27:11

US3012329

Folder: SAE USA-US006-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:26

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	04 Mar 2021 14:59:12
User entered '4'	System	12 Feb 2021 18:08:31
User entered '3'	System	12 Feb 2021 17:29:37
User entered '2'	System	28 Jan 2021 21:35:54
User entered '1'	System	20 Jan 2021 13:27:11

US3012329

Folder: SAE USA-US006-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:26

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:29:22
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 13:27:06
User entered 'USA-US006-2021-MRNA-1273-P301000003'	System	20 Jan 2021 13:26:52

US3012329

Folder: SAE USA-US006-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:26

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:29:22
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:29:16
Un-reviewed for Safety.	System	03 Feb 2021 22:28:03
User entered 'No (N)'	System	03 Feb 2021 22:28:03
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 21:35:43
User entered 'Yes (Y)'	System	28 Jan 2021 20:11:03
User entered 'No (N)'	System	27 Jan 2021 20:08:04
Un-reviewed for Safety.	System	27 Jan 2021 18:01:47
User entered 'Yes (Y)'	System	27 Jan 2021 18:01:47
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 13:27:06
User entered 'No (N)'	System	20 Jan 2021 13:26:52

US3012329

Folder: SAE USA-US006-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:26

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:29:22
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 13:27:06
User entered 'No (N)'	System	20 Jan 2021 13:26:52

US3012329

Folder: SAE USA-US006-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:26

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:29:22
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 13:27:06
User entered 'No (N)'	System	20 Jan 2021 13:26:52

US3012329

Folder: SAE USA-US006-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:26

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:29:22
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	12 Feb 2021 17:29:12
Un-reviewed for Safety.	System	03 Feb 2021 22:28:03
User entered 'No (N)'	System	03 Feb 2021 22:28:03
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 21:35:43
User entered 'Yes (Y)'	System	28 Jan 2021 20:11:03
User entered 'No (N)'	System	27 Jan 2021 20:08:04
Un-reviewed for Safety.	System	27 Jan 2021 18:01:47
User entered 'Yes (Y)'	System	27 Jan 2021 18:01:47
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 13:27:06
User entered 'No (N)'	System	20 Jan 2021 13:26:52

US3012329

Folder: SAE USA-US006-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:26

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:29:22
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 13:27:06
User entered 'No (N)'	System	20 Jan 2021 13:26:52

US3012329

Folder: SAE USA-US006-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:26

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:29:22
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 13:27:06
User entered 'No (N)'	System	20 Jan 2021 13:26:52

US3012329

Folder: SAE USA-US006-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:26

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:29:22
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 13:27:06
User entered 'No (N)'	System	20 Jan 2021 13:26:52

US3012329

Folder: SAE USA-US006-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:26

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:29:22
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 13:27:06
User entered 'Laurence'	System	20 Jan 2021 13:26:52

US3012329

Folder: SAE USA-US006-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:26

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:29:22
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 13:27:06
User entered 'Chu'	System	20 Jan 2021 13:26:52

US3012329

Folder: SAE USA-US006-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:26

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:29:22
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 13:27:06
User entered '3100 Red River Street'	System	20 Jan 2021 13:26:52

US3012329

Folder: SAE USA-US006-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:26

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:29:22
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 13:27:06
User entered 'Austin'	System	20 Jan 2021 13:26:52

US3012329

Folder: SAE USA-US006-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:26

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:29:22
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 13:27:06
User entered 'TX'	System	20 Jan 2021 13:26:52

US3012329

Folder: SAE USA-US006-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:26

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:29:22
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 13:27:06
User entered '78705'	System	20 Jan 2021 13:26:52

US3012329

Folder: SAE USA-US006-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:26

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:29:22
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 21:35:43
User entered 'US'	System	20 Jan 2021 13:27:11

US3012329

Folder: SAE USA-US006-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:26

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	04 Mar 2021 14:59:12
User entered '4'	System	12 Feb 2021 18:08:31
User entered '3'	System	12 Feb 2021 17:29:37
User entered '2'	System	28 Jan 2021 21:35:54
User entered '1'	System	20 Jan 2021 13:27:11

US3012329

Folder: SAE USA-US006-2021-MRNA-1273-P301000003

Form: Safety Report Form (1)

Generated On: 11 Aug 2021 21:53:26

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:29:22
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered '20/Jan/2021 08:27'	(b) (4) System	20 Jan 2021 13:27:11

US3012329

Folder: SAE USA-US006-2021-MRNA-1273-P301000003

Form: Safety Report Form (1)

Generated On: 11 Aug 2021 21:53:26

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)	13 Apr 2021 17:29:22
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 21:35:43
User entered 'I'		20 Jan 2021 13:27:11

US3012329

Folder: SAE USA-US006-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:26

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:29:22
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 13:27:06
User entered 'USA-US006-2021-MRNA-1273-P301000003'	System	20 Jan 2021 13:26:52

US3012329

Folder: SAE USA-US006-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:26

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:29:22
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:29:16
Un-reviewed for Safety.	System	03 Feb 2021 22:28:03
User entered 'No (N)'	System	03 Feb 2021 22:28:03
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 21:35:43
User entered 'Yes (Y)'	System	28 Jan 2021 20:11:03
User entered 'No (N)'	System	27 Jan 2021 20:08:04
Un-reviewed for Safety.	System	27 Jan 2021 18:01:47
User entered 'Yes (Y)'	System	27 Jan 2021 18:01:47
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 13:27:06
User entered 'No (N)'	System	20 Jan 2021 13:26:52

US3012329

Folder: SAE USA-US006-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:26

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:29:22
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 13:27:06
User entered 'No (N)'	System	20 Jan 2021 13:26:52

US3012329

Folder: SAE USA-US006-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:26

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:29:22
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 13:27:06
User entered 'No (N)'	System	20 Jan 2021 13:26:52

US3012329

Folder: SAE USA-US006-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:26

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:29:22
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:29:12
Un-reviewed for Safety.	System	03 Feb 2021 22:28:03
User entered 'No (N)'	System	03 Feb 2021 22:28:03
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 21:35:43
User entered 'Yes (Y)'	System	28 Jan 2021 20:11:03
User entered 'No (N)'	System	27 Jan 2021 20:08:04
Un-reviewed for Safety.	System	27 Jan 2021 18:01:47
User entered 'Yes (Y)'	System	27 Jan 2021 18:01:47
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 13:27:06
User entered 'No (N)'	System	20 Jan 2021 13:26:52

US3012329

Folder: SAE USA-US006-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:26

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:29:22
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 13:27:06
User entered 'No (N)'	System	20 Jan 2021 13:26:52

US3012329

Folder: SAE USA-US006-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:26

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:29:22
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 13:27:06
User entered 'No (N)'	System	20 Jan 2021 13:26:52

US3012329

Folder: SAE USA-US006-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:26

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:29:22
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 13:27:06
User entered 'No (N)'	System	20 Jan 2021 13:26:52

US3012329

Folder: SAE USA-US006-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:26

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:29:22
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 13:27:06
User entered 'Laurence'	System	20 Jan 2021 13:26:52

US3012329

Folder: SAE USA-US006-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:26

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:29:22
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 13:27:06
User entered 'Chu'	System	20 Jan 2021 13:26:52

US3012329

Folder: SAE USA-US006-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:26

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:29:22
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 13:27:06
User entered '3100 Red River Street'	System	20 Jan 2021 13:26:52

US3012329

Folder: SAE USA-US006-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:26

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:29:22
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 13:27:06
User entered 'Austin'	System	20 Jan 2021 13:26:52

US3012329

Folder: SAE USA-US006-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:26

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:29:22
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 13:27:06
User entered 'TX'	System	20 Jan 2021 13:26:52

US3012329

Folder: SAE USA-US006-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:26

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:29:22
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 13:27:06
User entered '78705'	System	20 Jan 2021 13:26:52

US3012329

Folder: SAE USA-US006-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:26

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:29:22
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 21:35:43
User entered 'US'	System	20 Jan 2021 13:27:11

US3012329

Folder: SAE USA-US006-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:26

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	04 Mar 2021 14:59:12
User entered '4'	System	12 Feb 2021 18:08:31
User entered '3'	System	12 Feb 2021 17:29:37
User entered '2'	System	28 Jan 2021 21:35:54
User entered '1'	System	20 Jan 2021 13:27:11

US3012329

Folder: SAE USA-US006-2021-MRNA-1273-P301000003

Form: Safety Report Form (2)

Generated On: 11 Aug 2021 21:53:26

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:29:22
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered '28/Jan/2021 16:35'	(b) (4) System	28 Jan 2021 21:35:54

US3012329

Folder: SAE USA-US006-2021-MRNA-1273-P301000003

Form: Safety Report Form (2)

Generated On: 11 Aug 2021 21:53:26

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)	13 Apr 2021 17:29:22
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 21:36:00
User entered 'I'		28 Jan 2021 21:35:54

US3012329

Folder: SAE USA-US006-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:26

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:29:22
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 13:27:06
User entered 'USA-US006-2021-MRNA-1273-P301000003'	System	20 Jan 2021 13:26:52

US3012329

Folder: SAE USA-US006-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:26

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:29:22
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:29:16
Un-reviewed for Safety.	System	03 Feb 2021 22:28:03
User entered 'No (N)'	System	03 Feb 2021 22:28:03
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 21:35:43
User entered 'Yes (Y)'	System	28 Jan 2021 20:11:03
User entered 'No (N)'	System	27 Jan 2021 20:08:04
Un-reviewed for Safety.	System	27 Jan 2021 18:01:47
User entered 'Yes (Y)'	System	27 Jan 2021 18:01:47
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 13:27:06
User entered 'No (N)'	System	20 Jan 2021 13:26:52

US3012329

Folder: SAE USA-US006-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:26

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:29:22
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 13:27:06
User entered 'No (N)'	System	20 Jan 2021 13:26:52

US3012329

Folder: SAE USA-US006-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:26

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:29:22
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 13:27:06
User entered 'No (N)'	System	20 Jan 2021 13:26:52

US3012329

Folder: SAE USA-US006-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:26

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:29:22
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:29:12
Un-reviewed for Safety.	System	03 Feb 2021 22:28:03
User entered 'No (N)'	System	03 Feb 2021 22:28:03
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 21:35:43
User entered 'Yes (Y)'	System	28 Jan 2021 20:11:03
User entered 'No (N)'	System	27 Jan 2021 20:08:04
Un-reviewed for Safety.	System	27 Jan 2021 18:01:47
User entered 'Yes (Y)'	System	27 Jan 2021 18:01:47
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 13:27:06
User entered 'No (N)'	System	20 Jan 2021 13:26:52

US3012329

Folder: SAE USA-US006-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:26

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:29:22
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 13:27:06
User entered 'No (N)'	System	20 Jan 2021 13:26:52

US3012329

Folder: SAE USA-US006-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:26

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:29:22
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 13:27:06
User entered 'No (N)'	System	20 Jan 2021 13:26:52

US3012329

Folder: SAE USA-US006-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:26

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:29:22
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 13:27:06
User entered 'No (N)'	System	20 Jan 2021 13:26:52

US3012329

Folder: SAE USA-US006-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:26

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:29:22
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 13:27:06
User entered 'Laurence'	System	20 Jan 2021 13:26:52

US3012329

Folder: SAE USA-US006-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:26

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:29:22
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 13:27:06
User entered 'Chu'	System	20 Jan 2021 13:26:52

US3012329

Folder: SAE USA-US006-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:26

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:29:22
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 13:27:06
User entered '3100 Red River Street'	System	20 Jan 2021 13:26:52

US3012329

Folder: SAE USA-US006-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:26

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:29:22
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 13:27:06
User entered 'Austin'	System	20 Jan 2021 13:26:52

US3012329

Folder: SAE USA-US006-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:26

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:29:22
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 13:27:06
User entered 'TX'	System	20 Jan 2021 13:26:52

US3012329

Folder: SAE USA-US006-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:26

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:29:22
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 13:27:06
User entered '78705'	System	20 Jan 2021 13:26:52

US3012329

Folder: SAE USA-US006-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:26

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:29:22
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 21:35:43
User entered 'US'	System	20 Jan 2021 13:27:11

US3012329

Folder: SAE USA-US006-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:26

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	04 Mar 2021 14:59:12
User entered '4'	System	12 Feb 2021 18:08:31
User entered '3'	System	12 Feb 2021 17:29:37
User entered '2'	System	28 Jan 2021 21:35:54
User entered '1'	System	20 Jan 2021 13:27:11

US3012329

Folder: SAE USA-US006-2021-MRNA-1273-P301000003

Form: Safety Report Form (3)

Generated On: 11 Aug 2021 21:53:26

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:29:22
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered '12/Feb/2021 12:29'	(b) (4) System	12 Feb 2021 17:29:37

US3012329

Folder: SAE USA-US006-2021-MRNA-1273-P301000003

Form: Safety Report Form (3)

Generated On: 11 Aug 2021 21:53:26

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)	13 Apr 2021 17:29:22
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 14:58:56
User entered '1'		12 Feb 2021 17:29:37

US3012329

Folder: SAE USA-US006-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:26

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:29:22
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 13:27:06
User entered 'USA-US006-2021-MRNA-1273-P301000003'	System	20 Jan 2021 13:26:52

US3012329

Folder: SAE USA-US006-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:26

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:29:22
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:29:16
Un-reviewed for Safety.	System	03 Feb 2021 22:28:03
User entered 'No (N)'	System	03 Feb 2021 22:28:03
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 21:35:43
User entered 'Yes (Y)'	System	28 Jan 2021 20:11:03
User entered 'No (N)'	System	27 Jan 2021 20:08:04
Un-reviewed for Safety.	System	27 Jan 2021 18:01:47
User entered 'Yes (Y)'	System	27 Jan 2021 18:01:47
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 13:27:06
User entered 'No (N)'	System	20 Jan 2021 13:26:52

US3012329

Folder: SAE USA-US006-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:26

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:29:22
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 13:27:06
User entered 'No (N)'	System	20 Jan 2021 13:26:52

US3012329

Folder: SAE USA-US006-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:26

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:29:22
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 13:27:06
User entered 'No (N)'	System	20 Jan 2021 13:26:52

US3012329

Folder: SAE USA-US006-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:26

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:29:22
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:29:12
Un-reviewed for Safety.	System	03 Feb 2021 22:28:03
User entered 'No (N)'	System	03 Feb 2021 22:28:03
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 21:35:43
User entered 'Yes (Y)'	System	28 Jan 2021 20:11:03
User entered 'No (N)'	System	27 Jan 2021 20:08:04
Un-reviewed for Safety.	System	27 Jan 2021 18:01:47
User entered 'Yes (Y)'	System	27 Jan 2021 18:01:47
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 13:27:06
User entered 'No (N)'	System	20 Jan 2021 13:26:52

US3012329

Folder: SAE USA-US006-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:26

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:29:22
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 13:27:06
User entered 'No (N)'	System	20 Jan 2021 13:26:52

US3012329

Folder: SAE USA-US006-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:26

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:29:22
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 13:27:06
User entered 'No (N)'	System	20 Jan 2021 13:26:52

US3012329

Folder: SAE USA-US006-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:26

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:29:22
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 13:27:06
User entered 'No (N)'	System	20 Jan 2021 13:26:52

US3012329

Folder: SAE USA-US006-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:26

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:29:22
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 13:27:06
User entered 'Laurence'	System	20 Jan 2021 13:26:52

US3012329

Folder: SAE USA-US006-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:26

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:29:22
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 13:27:06
User entered 'Chu'	System	20 Jan 2021 13:26:52

US3012329

Folder: SAE USA-US006-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:26

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:29:22
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 13:27:06
User entered '3100 Red River Street'	System	20 Jan 2021 13:26:52

US3012329

Folder: SAE USA-US006-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:26

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:29:22
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 13:27:06
User entered 'Austin'	System	20 Jan 2021 13:26:52

US3012329

Folder: SAE USA-US006-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:26

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:29:22
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 13:27:06
User entered 'TX'	System	20 Jan 2021 13:26:52

US3012329

Folder: SAE USA-US006-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:26

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:29:22
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 13:27:06
User entered '78705'	System	20 Jan 2021 13:26:52

US3012329

Folder: SAE USA-US006-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:26

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:29:22
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 21:35:43
User entered 'US'	System	20 Jan 2021 13:27:11

US3012329

Folder: SAE USA-US006-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:26

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	04 Mar 2021 14:59:12
User entered '4'	System	12 Feb 2021 18:08:31
User entered '3'	System	12 Feb 2021 17:29:37
User entered '2'	System	28 Jan 2021 21:35:54
User entered '1'	System	20 Jan 2021 13:27:11

US3012329

Folder: SAE USA-US006-2021-MRNA-1273-P301000003

Form: Safety Report Form (4)

Generated On: 11 Aug 2021 21:53:26

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:29:22
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered '12/Feb/2021 13:08'	(b) (4) System	12 Feb 2021 18:08:31

US3012329

Folder: SAE USA-US006-2021-MRNA-1273-P301000003

Form: Safety Report Form (4)

Generated On: 11 Aug 2021 21:53:26

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)	13 Apr 2021 17:29:22
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 14:58:56
User entered 'I'		12 Feb 2021 18:08:31

US3012329

Folder: SAE USA-US006-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:26

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:29:22
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 13:27:06
User entered 'USA-US006-2021-MRNA-1273-P301000003'	System	20 Jan 2021 13:26:52

US3012329

Folder: SAE USA-US006-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:26

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:29:22
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:29:16
Un-reviewed for Safety.	System	03 Feb 2021 22:28:03
User entered 'No (N)'	System	03 Feb 2021 22:28:03
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 21:35:43
User entered 'Yes (Y)'	System	28 Jan 2021 20:11:03
User entered 'No (N)'	System	27 Jan 2021 20:08:04
Un-reviewed for Safety.	System	27 Jan 2021 18:01:47
User entered 'Yes (Y)'	System	27 Jan 2021 18:01:47
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 13:27:06
User entered 'No (N)'	System	20 Jan 2021 13:26:52

US3012329

Folder: SAE USA-US006-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:26

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:29:22
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 13:27:06
User entered 'No (N)'	System	20 Jan 2021 13:26:52

US3012329

Folder: SAE USA-US006-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:26

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:29:22
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 13:27:06
User entered 'No (N)'	System	20 Jan 2021 13:26:52

US3012329

Folder: SAE USA-US006-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:26

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:29:22
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:29:12
Un-reviewed for Safety.	System	03 Feb 2021 22:28:03
User entered 'No (N)'	System	03 Feb 2021 22:28:03
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 21:35:43
User entered 'Yes (Y)'	System	28 Jan 2021 20:11:03
User entered 'No (N)'	System	27 Jan 2021 20:08:04
Un-reviewed for Safety.	System	27 Jan 2021 18:01:47
User entered 'Yes (Y)'	System	27 Jan 2021 18:01:47
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 13:27:06
User entered 'No (N)'	System	20 Jan 2021 13:26:52

US3012329

Folder: SAE USA-US006-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:26

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:29:22
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 13:27:06
User entered 'No (N)'	System	20 Jan 2021 13:26:52

US3012329

Folder: SAE USA-US006-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:26

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:29:22
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 13:27:06
User entered 'No (N)'	System	20 Jan 2021 13:26:52

US3012329

Folder: SAE USA-US006-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:26

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:29:22
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 13:27:06
User entered 'No (N)'	System	20 Jan 2021 13:26:52

US3012329

Folder: SAE USA-US006-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:26

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:29:22
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 13:27:06
User entered 'Laurence'	System	20 Jan 2021 13:26:52

US3012329

Folder: SAE USA-US006-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:26

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:29:22
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 13:27:06
User entered 'Chu'	System	20 Jan 2021 13:26:52

US3012329

Folder: SAE USA-US006-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:26

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:29:22
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 13:27:06
User entered '3100 Red River Street'	System	20 Jan 2021 13:26:52

US3012329

Folder: SAE USA-US006-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:26

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:29:22
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 13:27:06
User entered 'Austin'	System	20 Jan 2021 13:26:52

US3012329

Folder: SAE USA-US006-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:26

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:29:22
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 13:27:06
User entered 'TX'	System	20 Jan 2021 13:26:52

US3012329

Folder: SAE USA-US006-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:26

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:29:22
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 13:27:06
User entered '78705'	System	20 Jan 2021 13:26:52

US3012329

Folder: SAE USA-US006-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:26

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:29:22
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 21:35:43
User entered 'US'	System	20 Jan 2021 13:27:11

US3012329

Folder: SAE USA-US006-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:26

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	04 Mar 2021 14:59:12
User entered '4'	System	12 Feb 2021 18:08:31
User entered '3'	System	12 Feb 2021 17:29:37
User entered '2'	System	28 Jan 2021 21:35:54
User entered '1'	System	20 Jan 2021 13:27:11

US3012329

Folder: SAE USA-US006-2021-MRNA-1273-P301000003

Form: Safety Report Form (5)

Generated On: 11 Aug 2021 21:53:26

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:29:22
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered '04/Mar/2021 08:59'	(b) (4) System	04 Mar 2021 14:59:12

US3012329

Folder: SAE USA-US006-2021-MRNA-1273-P301000003

Form: Safety Report Form (5)

Generated On: 11 Aug 2021 21:53:26

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)	13 Apr 2021 17:29:22
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:15:03
User entered 'I'	(b) (4), (b) (6)	04 Mar 2021 14:59:12