

US3012171 (Prod: Benchmark Research-Austin)

Generated By: KC Joubran

Generated On: 09 Jun 2021 14:47:42

All time stamps listed in this document are displayed in GMT

US3012171

Form: Participant Creation

Data signed: (b) (4) 26 Mar 2021 00:56:18

Generated On: 09 Jun 2021 14:47:42

Participant ID

US3012171

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

US3012171

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 20:33:39

Generated On: 09 Jun 2021 14:47:42

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	18 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 12 Feb 2021 20:33:39

Generated On: 09 Jun 2021 14:47:42

Date of Birth (MMM yyyy)	(b) (6) 1956
Age	64
Age Units	YEARS
Age (Derived)	64
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 12 Feb 2021 20:33:39

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Date of Informed Consent (<i>dd MMM yyyy</i>)	18 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/>
	Amendment 2 <input checked="" type="radio"/>
	Amendment 3 <input type="radio"/>
	Amendment 4 <input type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 12 Feb 2021 20:33:39

Generated On: 09 Jun 2021 14:47:42

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 20:33:39

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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 20:33:39

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Condition	SEASONAL ALLERGIES, UNSPECIFIED
Start date (dd MMM yyyy)	UN UNK 1960
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 1960
Start Year (derived)	1960
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 12 Feb 2021 20:33:39

Generated On: 09 Jun 2021 14:47:42

Condition	ALLERGY TO CITRUS
Start date (dd MMM yyyy)	UN UNK 1970
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 1970
Start Year (derived)	1970
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 12 Feb 2021 20:33:39

Generated On: 09 Jun 2021 14:47:42

Condition	OBESITY
Start date (dd MMM yyyy)	UN UNK 2016
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 2016
Start Year (derived)	2016
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 12 Feb 2021 20:33:39

Generated On: 09 Jun 2021 14:47:42

Condition	DIABETES, TYPE II
Start date (dd MMM yyyy)	UN UNK 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 12 Feb 2021 20:33:39

Generated On: 09 Jun 2021 14:47:42

Condition	OVERACTIVE BLADDER
Start date (dd MMM yyyy)	UN UNK 2017
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 2017
Start Year (derived)	2017
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 12 Feb 2021 20:33:39

Generated On: 09 Jun 2021 14:47:42

Condition	OSTEOARTHRITIS, BILATERAL FINGERS
Start date (dd MMM yyyy)	UN UNK 1973
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 1973
Start Year (derived)	1973
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 12 Feb 2021 20:33:39

Generated On: 09 Jun 2021 14:47:42

Condition	BACK PAIN, LUMBAR
Start date (dd MMM yyyy)	12 SEP 2018
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 NOV 2018
Stop date completely unknown	False
Start Month and Year (derived)	SEP 2018
Start Year (derived)	2018
Stop Month and Year (derived)	NOV 2018
Stop Year (derived)	2018

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 12 Feb 2021 20:33:39

Generated On: 09 Jun 2021 14:47:42

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	18 AUG 2020
Time of assessment (00:00-23:59)	14:26 (24 HR)
Vital Signs Date and Time (derived)	18 AUG 2020 14:26
Height (xxx.x)	66.5 in
Weight (xxx.x)	245.0 lb
BMI (xxx.x)	39.03307 kg/m ²
BMI units	KG/M2
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	ND - Not Done
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	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 20:33:39

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Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

18 AUG 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 12 Feb 2021 20:33:39

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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 20:33:39

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 20:33:39

Generated On: 09 Jun 2021 14:47:42

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	18 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 12 Feb 2021 20:33:39

Generated On: 09 Jun 2021 14:47:42

What was the date of randomization? (dd MMM yyyy) 18 AUG 2020

What was the participant's randomization number? 144213

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 20:33:39

Generated On: 09 Jun 2021 14:47:42

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 20:33:39

Generated On: 09 Jun 2021 14:47:42

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)	18 AUG 2020
Time of assessment (00:00-23:59)	14:26 (24 HR)
Vital Signs Date and Time (derived)	18 AUG 2020 14:26
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	98 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	111 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	69 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 20:33:39

Generated On: 09 Jun 2021 14:47:42

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)	18 AUG 2020
Time of assessment (00:00-23:59)	16:48 (24 HR)
Vital Signs Date and Time (derived)	18 AUG 2020 16:48
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	88 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 20:33:39

Generated On: 09 Jun 2021 14:47:42

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 20:33:39

Generated On: 09 Jun 2021 14:47:42

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) 18 AUG 2020

What was the treatment time? (00:00-23:59) 16:06 (24 HR)

Treatment Date and Time (derived) 18 AUG 2020 16:06

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 20:33:39

Generated On: 09 Jun 2021 14:47:42

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

18 AUG 2020

Collection time (00:00-23:59)

15:28 (24 HR)

Collection date and time (derived)

18 AUG 2020 15:28

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Feb 2021 20:33:39

Generated On: 09 Jun 2021 14:47:42

Collection date (dd MMM yyyy)			18 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	15:04	18 AUG 2020 15:04
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 20:33:39

Generated On: 09 Jun 2021 14:47:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

18 AUG 2020 16:38

PC Open Date & Time

18 AUG 2020 16:26

PC Close Date & Time

18 AUG 2020 18:56

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.8 °F

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

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

PC Time Stamp	18 AUG 2020 21:06
PC Open Date & Time	18 AUG 2020 19:51
PC Close Date & Time	19 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:47:42

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

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

20 AUG 2020 00:00

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:47:42

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

20 AUG 2020 21:18

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:47:42

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

97.8 °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

21 AUG 2020 23:24

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3012171

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:47:42

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

97.8 °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

22 AUG 2020 18:41

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3012171

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:47:42

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

97.8 °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

24 AUG 2020 05:01

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3012171

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:47:42

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

97.6 °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

25 AUG 2020 02:09

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3012171

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

18 AUG 2020 16:39

PC Open Date & Time

18 AUG 2020 16:26

PC Close Date & Time

18 AUG 2020 18:56

US3012171

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:47:42

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

18 AUG 2020 21:06

PC Open Date & Time

18 AUG 2020 19:51

PC Close Date & Time

19 AUG 2020 11:59

US3012171

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

20 AUG 2020 00:00

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3012171

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:47:42

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

20 AUG 2020 21:18

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3012171

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:47:42

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

21 AUG 2020 23:25

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3012171

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:47:42

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

22 AUG 2020 18:41

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3012171

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:47:42

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

24 AUG 2020 05:02

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3012171

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

25 AUG 2020 02:10

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3012171

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:47:42

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 ☐

US3012171

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:47:42

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

No ☒

Yes ☐

PC Time stamp	18 AUG 2020 16:40
PC Open Date & Time	18 AUG 2020 16:26
PC Close Date & Time	18 AUG 2020 18:56

US3012171

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:47:42

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 ☐

US3012171

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:47:42

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

No ☒

Yes ☐

PC Time stamp	18 AUG 2020 21:07
PC Open Date & Time	18 AUG 2020 19:51
PC Close Date & Time	19 AUG 2020 11:59

US3012171

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:47:42

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 ☒

US3012171

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:47:42

Yes <input type="checkbox"/>	
PC Time stamp	20 AUG 2020 00:01
PC Open Date & Time	19 AUG 2020 12:00
PC Close Date & Time	20 AUG 2020 11:59

US3012171

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:47:42

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 ☒

US3012171

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:47:42

Yes <input type="checkbox"/>	
PC Time stamp	20 AUG 2020 21:19
PC Open Date & Time	20 AUG 2020 12:00
PC Close Date & Time	21 AUG 2020 11:59

US3012171

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:47:42

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 ☒

US3012171

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:47:42

Yes <input type="checkbox"/>	
PC Time stamp	21 AUG 2020 23:25
PC Open Date & Time	21 AUG 2020 12:00
PC Close Date & Time	22 AUG 2020 11:59

US3012171

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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US3012171

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:47:42

Yes <input type="checkbox"/>	
PC Time stamp	22 AUG 2020 18:41
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

US3012171

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:47:42

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 ☒

US3012171

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:47:42

Yes <input type="checkbox"/>	
PC Time stamp	24 AUG 2020 05:02
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

US3012171

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:47:42

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 ☒

US3012171

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:47:42

Yes <input type="checkbox"/>	
PC Time stamp	25 AUG 2020 02:10
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59

US3012171

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 20:33:39

Generated On: 09 Jun 2021 14:47:42

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

31 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3012171

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 20:33:39

Generated On: 09 Jun 2021 14:47:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3012171

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 20:33:39

Generated On: 09 Jun 2021 14:47:42

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

2 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3012171

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 20:33:39

Generated On: 09 Jun 2021 14:47:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3012171

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 20:33:39

Generated On: 09 Jun 2021 14:47:42

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

8 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3012171

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 20:33:39

Generated On: 09 Jun 2021 14:47:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3012171

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 20:33:39

Generated On: 09 Jun 2021 14:47:42

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	15 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3012171

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Feb 2021 20:33:40

Generated On: 09 Jun 2021 14:47:42

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)	10:10 (24 HR)
Vital Signs Date and Time (derived)	15 SEP 2020 10:10
Temperature (xxx.x)	99.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	101 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	115 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	75 mmHg
Diastolic Blood Pressure units	MMHG

US3012171

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 20:33:40

Generated On: 09 Jun 2021 14:47:42

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	15 SEP 2020
Time of assessment (00:00-23:59)	11:46 (24 HR)
Vital Signs Date and Time (derived)	15 SEP 2020 11:46
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	96 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	108 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	77 mmHg
Diastolic Blood Pressure units	MMHG

US3012171

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 20:33:39

Generated On: 09 Jun 2021 14:47:42

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.

US3012171

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 20:33:39

Generated On: 09 Jun 2021 14:47:42

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) 11:01 (24 HR)

Treatment Date and Time (derived) 15 SEP 2020 11:01

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

What was the frequency of the study treatment dosing? ONCE

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

US3012171

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 20:33:39

Generated On: 09 Jun 2021 14:47:42

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

15 SEP 2020

Collection time (00:00-23:59)

10:37 (24 HR)

Collection date and time (derived)

15 SEP 2020 10:37

US3012171

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Feb 2021 20:33:39

Generated On: 09 Jun 2021 14:47:42

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	10:24	15 SEP 2020 10:24
Nasopharyngeal Swab 2	No		

US3012171

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 20:33:39

Generated On: 09 Jun 2021 14:47:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3012171

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 SEP 2020 11:37

PC Open Date & Time

15 SEP 2020 11:21

PC Close Date & Time

15 SEP 2020 13:51

US3012171

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:47:42

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	15 SEP 2020 20:45
PC Open Date & Time	15 SEP 2020 14:46
PC Close Date & Time	16 SEP 2020 11:59

US3012171

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:47:42

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

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 SEP 2020 14:22

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3012171

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:47:42

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

97.4 °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

17 SEP 2020 23:13

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3012171

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:47:42

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

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 SEP 2020 01:13

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3012171

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

20 SEP 2020 00:00

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3012171

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:47:42

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

97.5 °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

20 SEP 2020 22:08

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3012171

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:47:42

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

97.6 °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

22 SEP 2020 10:42

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3012171

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:47:42

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 11:37

PC Open Date & Time

15 SEP 2020 11:21

PC Close Date & Time

15 SEP 2020 13:51

US3012171

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

15 SEP 2020 20:46

PC Open Date & Time

15 SEP 2020 14:46

PC Close Date & Time

16 SEP 2020 11:59

US3012171

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:47:42

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 14:23

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3012171

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

17 SEP 2020 23:13

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3012171

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

DAY 4

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

19 SEP 2020 01:13

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3012171

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

DAY 5

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

20 SEP 2020 00:00

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3012171

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

20 SEP 2020 22:09

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3012171

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

22 SEP 2020 10:42

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3012171

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:47:42

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 ☐

US3012171

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:47:42

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

No ☒

Yes ☐

PC Time stamp	15 SEP 2020 11:38
PC Open Date & Time	15 SEP 2020 11:21
PC Close Date & Time	15 SEP 2020 13:51

US3012171

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:47:42

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 ☐

US3012171

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:47:42

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

No ☒

Yes ☐

PC Time stamp	15 SEP 2020 20:46
PC Open Date & Time	15 SEP 2020 14:46
PC Close Date & Time	16 SEP 2020 11:59

US3012171

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:47:42

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 ☒

US3012171

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:47:42

Yes <input type="checkbox"/>	
PC Time stamp	16 SEP 2020 14:23
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

US3012171

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:47:42

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 ☒

US3012171

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:47:42

Yes <input type="checkbox"/>	
PC Time stamp	17 SEP 2020 23:14
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

US3012171

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:47:42

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 ☒

US3012171

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:47:42

Yes <input type="checkbox"/>	
PC Time stamp	19 SEP 2020 01:14
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

US3012171

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:47:42

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 ☒

US3012171

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:47:42

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

US3012171

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:47:42

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 ☒

US3012171

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:47:42

Yes <input type="checkbox"/>	
PC Time stamp	20 SEP 2020 22:09
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

US3012171

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:47:42

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 ☒

US3012171

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:47:42

Yes <input type="checkbox"/>	
PC Time stamp	22 SEP 2020 10:43
PC Open Date & Time	21 SEP 2020 12:00
PC Close Date & Time	22 SEP 2020 11:59

US3012171

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 20:33:39

Generated On: 09 Jun 2021 14:47:42

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3012171

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 20:33:39

Generated On: 09 Jun 2021 14:47:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3012171

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 20:33:39

Generated On: 09 Jun 2021 14:47:42

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

US3012171

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 20:33:39

Generated On: 09 Jun 2021 14:47:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3012171

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 20:33:39

Generated On: 09 Jun 2021 14:47:42

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

US3012171

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 20:33:39

Generated On: 09 Jun 2021 14:47:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3012171

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 20:34:05

Generated On: 09 Jun 2021 14:47:42

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

US3012171

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Feb 2021 20:34:05

Generated On: 09 Jun 2021 14:47:42

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)	11:24 (24 HR)
Vital Signs Date and Time (derived)	13 OCT 2020 11:24
Temperature (xxx.x)	99.1 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	90 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	119 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3012171

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 20:33:40

Generated On: 09 Jun 2021 14:47:42

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.

US3012171

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 20:33:40

Generated On: 09 Jun 2021 14:47:42

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

13 OCT 2020

Collection time (00:00-23:59)

11:45 (24 HR)

Collection date and time (derived)

13 OCT 2020 11:45

US3012171

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 20:33:40

Generated On: 09 Jun 2021 14:47:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3012171

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

DAY 64

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 OCT 2020 00:01:30

Patient Cloud Open Date & Time

18 OCT 2020 00:01

Patient Cloud Close Date & Time

22 OCT 2020 23:59

US3012171

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 OCT 2020 11:37:19

Patient Cloud Open Date & Time

25 OCT 2020 00:01

Patient Cloud Close Date & Time

29 OCT 2020 23:59

US3012171

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3012171

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

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

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

Date and time of submission

Patient Cloud Open Date & Time

01 NOV 2020 00:01

Patient Cloud Close Date & Time

05 NOV 2020 23:59

US3012171

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

DAY 92

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 NOV 2020 18:19:03

Patient Cloud Open Date & Time

15 NOV 2020 00:01

Patient Cloud Close Date & Time

19 NOV 2020 23:59

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

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 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"/>

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

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

[Patient Cloud Close Date & Time](#)

23 NOV 2020 23:59

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

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

26 NOV 2020 00:01:54

Patient Cloud Open Date & Time

26 NOV 2020 00:01

Patient Cloud Close Date & Time

30 NOV 2020 23:59

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

DAY 110

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 DEC 2020 05:15:30

Patient Cloud Open Date & Time

03 DEC 2020 00:01

Patient Cloud Close Date & Time

07 DEC 2020 23:59

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

10 DEC 2020 04:28:58

Patient Cloud Open Date & Time

10 DEC 2020 00:01

Patient Cloud Close Date & Time

14 DEC 2020 23:59

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

DAY 124

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 DEC 2020 14:31:07

Patient Cloud Open Date & Time

17 DEC 2020 00:01

Patient Cloud Close Date & Time

21 DEC 2020 23:59

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

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

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

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

[Patient Cloud Close Date & Time](#)

28 DEC 2020 23:59

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 JAN 2021 17:39:13

Patient Cloud Open Date & Time

31 DEC 2020 00:01

Patient Cloud Close Date & Time

04 JAN 2021 23:59

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

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 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	07 JAN 2021 22:07:47
Patient Cloud Open Date & Time	07 JAN 2021 00:01
Patient Cloud Close Date & Time	11 JAN 2021 23:59

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

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 <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	15 JAN 2021 05:50:27
Patient Cloud Open Date & Time	14 JAN 2021 00:01
Patient Cloud Close Date & Time	18 JAN 2021 23:59

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 JAN 2021 02:56:48

Patient Cloud Open Date & Time

21 JAN 2021 00:01

Patient Cloud Close Date & Time

25 JAN 2021 23:59

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

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

28 JAN 2021 00:01:34

Patient Cloud Open Date & Time

28 JAN 2021 00:01

Patient Cloud Close Date & Time

01 FEB 2021 23:59

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

06 FEB 2021 05:37:55

Patient Cloud Open Date & Time

04 FEB 2021 00:01

Patient Cloud Close Date & Time

08 FEB 2021 23:59

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

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

[Patient Cloud Open Date & Time](#)

11 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

15 FEB 2021 23:59

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

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

[Patient Cloud Close Date & Time](#)

22 FEB 2021 23:59

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

DAY 194

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 MAR 2021 13:56:10

Patient Cloud Open Date & Time

25 FEB 2021 00:01

Patient Cloud Close Date & Time

01 MAR 2021 23:59

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

05 MAR 2021 18:04:58

Patient Cloud Open Date & Time

04 MAR 2021 00:01

Patient Cloud Close Date & Time

08 MAR 2021 23:59

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

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 <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 13:14:42
Patient Cloud Open Date & Time	11 MAR 2021 00:01
Patient Cloud Close Date & Time	15 MAR 2021 23:59

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

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 <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	19 MAR 2021 18:33:58
Patient Cloud Open Date & Time	18 MAR 2021 00:01
Patient Cloud Close Date & Time	22 MAR 2021 23:59

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

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

29 MAR 2021 03:49:36

Patient Cloud Open Date & Time

25 MAR 2021 00:01

Patient Cloud Close Date & Time

29 MAR 2021 23:59

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

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

01 APR 2021 17:17:56

Patient Cloud Open Date & Time

01 APR 2021 00:01

Patient Cloud Close Date & Time

05 APR 2021 23:59

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

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 ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-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 15:08:11

Patient Cloud Open Date & Time

08 APR 2021 00:01

Patient Cloud Close Date & Time

12 APR 2021 23:59

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 APR 2021 00:18:25

Patient Cloud Open Date & Time

15 APR 2021 00:01

Patient Cloud Close Date & Time

19 APR 2021 23:59

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 APR 2021 17:22:16

Patient Cloud Open Date & Time

22 APR 2021 00:01

Patient Cloud Close Date & Time

26 APR 2021 23:59

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

DAY 257

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 APR 2021 12:45:07

Patient Cloud Open Date & Time

29 APR 2021 00:01

Patient Cloud Close Date & Time

03 MAY 2021 23:59

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

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"/>

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

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

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

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"/>

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

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

[Patient Cloud Close Date & Time](#)

17 MAY 2021 23:59

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

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 ☐

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

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

[Patient Cloud Close Date & Time](#)

24 MAY 2021 23:59

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

DAY 285

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

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

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

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

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

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

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

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

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

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

[Patient Cloud Close Date & Time](#)

31 MAY 2021 23:59

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

DAY 292

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

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

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

DAY 299

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

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

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

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 ☐

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

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

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

DAY 313

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

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

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

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

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

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

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

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

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

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

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

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

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

05 JUL 2021 23:59

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

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°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 ☐

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

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

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

DAY 334

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

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

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

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

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

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

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

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"/>

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

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

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

DAY 355

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

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

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

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

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

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

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

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

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

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

[Patient Cloud Close Date & Time](#)

09 AUG 2021 23:59

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

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 ☐

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

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

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

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 ☐

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

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

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

DAY 376

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

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

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

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

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

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

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

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

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

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

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT	DAY 383
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

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

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

DAY 390

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

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

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

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

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

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

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

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

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

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

[Patient Cloud Close Date & Time](#)

13 SEP 2021 23:59

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

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 ☐

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

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

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

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

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

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

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT	DAY 411
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

04 OCT 2021 23:59

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT	DAY 418
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	07 OCT 2021 00:01
Patient Cloud Close Date & Time	11 OCT 2021 23:59

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

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

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

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

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT	DAY 432
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

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

[Patient Cloud Close Date & Time](#)

25 OCT 2021 23:59

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

DAY 439

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

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

[Patient Cloud Close Date & Time](#)

01 NOV 2021 23:59

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

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

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

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

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

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 ☐

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

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

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

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

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

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

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

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

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

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

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT	DAY 474
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

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

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

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

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

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

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

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

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

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

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

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

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

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

[Patient Cloud Close Date & Time](#)

27 DEC 2021 23:59

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

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 ☐

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

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

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

DAY 509

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

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

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

DAY 516

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

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

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

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 ☐

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

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

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

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

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

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

[Patient Cloud Close Date & Time](#)

31 JAN 2022 23:59

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

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 ☐

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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 FEB 2022 00:01
Patient Cloud Close Date & Time	07 FEB 2022 23:59

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

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

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

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

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

DAY 551

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

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

[Patient Cloud Close Date & Time](#)

21 FEB 2022 23:59

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

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 ☐

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

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

[Patient Cloud Open Date & Time](#)

24 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

28 FEB 2022 23:59

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

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 ☐

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

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

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07 MAR 2022 23:59

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

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 ☐

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

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

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

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°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 ☐

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

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

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

DAY 586

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

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

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

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

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

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

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

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

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

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

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

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 ☐

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

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

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

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

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

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

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

DAY 607

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

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

[Patient Cloud Close Date & Time](#)

18 APR 2022 23:59

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

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

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

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

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT	DAY 621
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

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

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

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

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

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

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

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

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

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

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

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

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

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

[Patient Cloud Open Date & Time](#)

19 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAY 2022 23:59

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT	DAY 649
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

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

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

DAY 656

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

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

[Patient Cloud Close Date & Time](#)

06 JUN 2022 23:59

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

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

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

DAY 670

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

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

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

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

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

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

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

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

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

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

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

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 ☐

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

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

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

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"/>

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

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

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

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="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"/>

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

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

[Patient Cloud Open Date & Time](#)

07 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

11 JUL 2022 23:59

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

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"/>

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

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

[Patient Cloud Close Date & Time](#)

18 JUL 2022 23:59

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

DAY 705

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

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

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

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

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

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

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

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

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

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

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

DAY 712

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

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

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

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

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

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

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

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

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

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

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT	DAY 719
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

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

[Patient Cloud Open Date & Time](#)

04 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

08 AUG 2022 23:59

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

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 ☐

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

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

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

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

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

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

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

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

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

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

[Patient Cloud Close Date & Time](#)

29 AUG 2022 23:59

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

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"/>

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

05 SEP 2022 23:59

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

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 ☐

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

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

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12 SEP 2022 23:59

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

DAY 761

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

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

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

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"/>

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

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

[Patient Cloud Open Date & Time](#)

22 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

26 SEP 2022 23:59

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

DAY 775

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

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

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

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 ☐

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

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

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

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 ☐

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

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

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

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

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

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

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

Date and time of submission	
Patient Cloud Open Date & Time	20 OCT 2022 00:01
Patient Cloud Close Date & Time	24 OCT 2022 23:59

US3012171

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 14:47:42

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		01 MAR 2021 13:56:21

US3012171

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 19:29:08

Generated On: 09 Jun 2021 14:47:42

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3012171

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 19:29:08

Generated On: 09 Jun 2021 14:47:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3012171

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 26 Mar 2021 00:56:19

Generated On: 09 Jun 2021 14:47:42

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 15 DEC 2020

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

Comments

If Contact Not Made, please provide Comments

US3012171

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 00:56:19

Generated On: 09 Jun 2021 14:47:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3012171

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 26 Mar 2021 00:56:19

Generated On: 09 Jun 2021 14:47:42

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 14 JAN 2021

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

Comments

If Contact Not Made, please provide Comments

US3012171

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 00:56:19

Generated On: 09 Jun 2021 14:47:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3012171

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 26 Mar 2021 00:56:19

Generated On: 09 Jun 2021 14:47:42

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3012171

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 00:56:19

Generated On: 09 Jun 2021 14:47:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3012171

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 26 Mar 2021 00:56:19

Generated On: 09 Jun 2021 14:47:42

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

Visit date (dd MMM yyyy)	23 MAR 2021
--------------------------	-------------

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

Folder OID	VISIT4
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US3012171

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 08 Apr 2021 14:53:56

Generated On: 09 Jun 2021 14:47:42

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	23 MAR 2021
Time of assessment (00:00-23:59)	12:00 (24 HR)
Vital Signs Date and Time (derived)	23 MAR 2021 12:00
Temperature (xxx.x)	99.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	94 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	106 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	69 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3012171

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Mar 2021 00:56:19

Generated On: 09 Jun 2021 14:47:42

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

23 MAR 2021

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

US3012171

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Mar 2021 00:56:19

Generated On: 09 Jun 2021 14:47:42

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	23 MAR 2021
Collection time (00:00-23:59)	12:31 (24 HR)
Collection date and time (derived)	23 MAR 2021 12:31

US3012171

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 00:56:19

Generated On: 09 Jun 2021 14:47:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3012171

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 15 Apr 2021 16:35:55

Generated On: 09 Jun 2021 14:47:42

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3012171

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 15 Apr 2021 16:35:55

Generated On: 09 Jun 2021 14:47:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3012171

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:47:42

Was Contact Attempted? Yes ☐
No ☐

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3012171

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:47:42

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: COVID-19 Contact

Data signed: (b) (4) 26 Mar 2021 00:56:18

Generated On: 09 Jun 2021 14:47:42

Date of Contact	14 JAN 2021
Time of Contact	17:45
Date and Time of Contact (derived)	14 JAN 2021 17:45
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>

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (1)

Data signed: (b) (4) 26 Mar 2021 00:56:18

Generated On: 09 Jun 2021 14:47:42

Symptom Day

Day 1	<input checked="" type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input 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"/>

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (1)

Data signed: (b) (4) 26 Mar 2021 00:56:18

Generated On: 09 Jun 2021 14:47:42

	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	31 DEC 2020
------	-------------

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

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

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

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

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 checked="" 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"/>

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (1)

Data signed: (b) (4) 26 Mar 2021 00:56:18

Generated On: 09 Jun 2021 14:47:42

	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 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"/>

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (1)

Data signed: (b) (4) 26 Mar 2021 00:56:18

Generated On: 09 Jun 2021 14:47:42

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

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (2)

Data signed: (b) (4) 26 Mar 2021 00:56:18

Generated On: 09 Jun 2021 14:47:42

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"/>

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (2)

Data signed: (b) (4) 26 Mar 2021 00:56:18

Generated On: 09 Jun 2021 14:47:42

	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	1 JAN 2021
------	------------

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

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

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

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

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 checked="" 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"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (2)

Data signed: (b) (4) 26 Mar 2021 00:56:18

Generated On: 09 Jun 2021 14:47:42

	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 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"/>

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (2)

Data signed: (b) (4) 26 Mar 2021 00:56:18

Generated On: 09 Jun 2021 14:47:42

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

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (3)

Data signed: (b) (4) 26 Mar 2021 00:56:18

Generated On: 09 Jun 2021 14:47:42

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"/>

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (3)

Data signed: (b) (4) 26 Mar 2021 00:56:18

Generated On: 09 Jun 2021 14:47:42

	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	2 JAN 2021
------	------------

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

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

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

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

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 checked="" 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"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (3)

Data signed: (b) (4) 26 Mar 2021 00:56:18

Generated On: 09 Jun 2021 14:47:42

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

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Form: Symptom Log (3)

Data signed: (b) (4) 26 Mar 2021 00:56:18

Generated On: 09 Jun 2021 14:47:42

Nasal Congestion	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" 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 14 Jan 2021

Form: Symptom Log (4)

Data signed: (b) (4) 26 Mar 2021 00:56:18

Generated On: 09 Jun 2021 14:47:42

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 14 Jan 2021

Form: Symptom Log (4)

Data signed: (b) (4) 26 Mar 2021 00:56:18

Generated On: 09 Jun 2021 14:47:42

	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	3 JAN 2021
------	------------

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

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

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

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

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 checked="" 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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Form: Symptom Log (4)

Data signed: (b) (4) 26 Mar 2021 00:56:18

Generated On: 09 Jun 2021 14:47:42

	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 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 14 Jan 2021

Form: Symptom Log (4)

Data signed: (b) (4) 26 Mar 2021 00:56:18

Generated On: 09 Jun 2021 14:47:42

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

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Form: Symptom Log (5)

Data signed: (b) (4) 26 Mar 2021 00:56:18

Generated On: 09 Jun 2021 14:47:42

Symptom Day

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

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Form: Symptom Log (5)

Data signed: (b) (4) 26 Mar 2021 00:56:18

Generated On: 09 Jun 2021 14:47:42

	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	4 JAN 2021	
Assessment Not Done	False	
O2 Saturation	<input type="text"/>	
O2 Saturation Units	<input type="text"/>	
Temperature	<input type="text"/>	
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 checked="" 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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Form: Symptom Log (5)

Data signed: (b) (4) 26 Mar 2021 00:56:18

Generated On: 09 Jun 2021 14:47:42

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

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Form: Symptom Log (5)

Data signed: (b) (4) 26 Mar 2021 00:56:18

Generated On: 09 Jun 2021 14:47:42

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

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Form: Symptom Log (6)

Data signed: (b) (4) 26 Mar 2021 00:56:18

Generated On: 09 Jun 2021 14:47:42

Symptom Day

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

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Form: Symptom Log (6)

Data signed: (b) (4) 26 Mar 2021 00:56:18

Generated On: 09 Jun 2021 14:47:42

	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	5 JAN 2021	
Assessment Not Done	False	
O2 Saturation	<input type="text"/>	
O2 Saturation Units	<input type="text"/>	
Temperature	<input type="text"/>	
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 checked="" 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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Form: Symptom Log (6)

Data signed: (b) (4) 26 Mar 2021 00:56:18

Generated On: 09 Jun 2021 14:47:42

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

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Form: Symptom Log (6)

Data signed: (b) (4) 26 Mar 2021 00:56:18

Generated On: 09 Jun 2021 14:47:42

Nasal Congestion	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" 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 14 Jan 2021

Form: Symptom Log (7)

Data signed: (b) (4) 26 Mar 2021 00:56:18

Generated On: 09 Jun 2021 14:47:42

Symptom Day

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

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Form: Symptom Log (7)

Data signed: (b) (4) 26 Mar 2021 00:56:18

Generated On: 09 Jun 2021 14:47:42

	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	6 JAN 2021	
Assessment Not Done	False	
O2 Saturation	<input type="text"/>	
O2 Saturation Units	<input type="text"/>	
Temperature	<input type="text"/>	
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 checked="" 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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Form: Symptom Log (7)

Data signed: (b) (4) 26 Mar 2021 00:56:18

Generated On: 09 Jun 2021 14:47:42

	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 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 14 Jan 2021

Form: Symptom Log (7)

Data signed: (b) (4) 26 Mar 2021 00:56:18

Generated On: 09 Jun 2021 14:47:42

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

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Form: Symptom Log (8)

Data signed: (b) (4) 26 Mar 2021 00:56:18

Generated On: 09 Jun 2021 14:47:42

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 14 Jan 2021

Form: Symptom Log (8)

Data signed: (b) (4) 26 Mar 2021 00:56:18

Generated On: 09 Jun 2021 14:47:42

	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	7 JAN 2021
------	------------

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

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

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

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

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 checked="" 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 14 Jan 2021

Form: Symptom Log (8)

Data signed: (b) (4) 26 Mar 2021 00:56:18

Generated On: 09 Jun 2021 14:47:42

	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 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 14 Jan 2021

Form: Symptom Log (8)

Data signed: (b) (4) 26 Mar 2021 00:56:18

Generated On: 09 Jun 2021 14:47:42

Nasal Congestion	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" 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 14 Jan 2021

Form: Symptom Log (9)

Data signed: (b) (4) 26 Mar 2021 00:56:18

Generated On: 09 Jun 2021 14:47:42

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 14 Jan 2021

Form: Symptom Log (9)

Data signed: (b) (4) 26 Mar 2021 00:56:18

Generated On: 09 Jun 2021 14:47:42

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

Date	8 JAN 2021
------	------------

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

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

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

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

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 checked="" 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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Form: Symptom Log (9)

Data signed: (b) (4) 26 Mar 2021 00:56:18

Generated On: 09 Jun 2021 14:47:42

	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 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 14 Jan 2021

Form: Symptom Log (9)

Data signed: (b) (4) 26 Mar 2021 00:56:18

Generated On: 09 Jun 2021 14:47:42

Nasal Congestion	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" 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 14 Jan 2021

Form: Symptom Log (10)

Data signed: (b) (4) 26 Mar 2021 00:56:18

Generated On: 09 Jun 2021 14:47:42

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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Form: Symptom Log (10)

Data signed: (b) (4) 26 Mar 2021 00:56:18

Generated On: 09 Jun 2021 14:47:42

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	9 JAN 2021	
Assessment Not Done	False	
O2 Saturation	<input type="text"/>	
O2 Saturation Units	<input type="text"/>	
Temperature	<input type="text"/>	
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 checked="" 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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Form: Symptom Log (10)

Data signed: (b) (4) 26 Mar 2021 00:56:18

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

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Form: Symptom Log (10)

Data signed: (b) (4) 26 Mar 2021 00:56:18

Generated On: 09 Jun 2021 14:47:42

Nasal Congestion

None ☐
Mild ☐
Moderate ☒
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☐
Mild ☐
Moderate ☒
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

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Form: Symptom Log (11)

Data signed: (b) (4) 26 Mar 2021 00:56:18

Generated On: 09 Jun 2021 14:47:42

Symptom Day

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

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Form: Symptom Log (11)

Data signed: (b) (4) 26 Mar 2021 00:56:18

Generated On: 09 Jun 2021 14:47:42

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	10 JAN 2021	
Assessment Not Done	False	
O2 Saturation	<input type="text"/>	
O2 Saturation Units	<input type="text"/>	
Temperature	<input type="text"/>	
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 checked="" 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 14 Jan 2021

Form: Symptom Log (11)

Data signed: (b) (4) 26 Mar 2021 00:56:18

Generated On: 09 Jun 2021 14:47:42

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (11)

Data signed: (b) (4) 26 Mar 2021 00:56:18

Generated On: 09 Jun 2021 14:47:42

Nasal Congestion	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" 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 14 Jan 2021

Form: Symptom Log (12)

Data signed: (b) (4) 26 Mar 2021 00:56:18

Generated On: 09 Jun 2021 14:47:42

Symptom Day

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

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (12)

Data signed: (b) (4) 26 Mar 2021 00:56:18

Generated On: 09 Jun 2021 14:47:42

	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	<input type="text"/>	
O2 Saturation Units	<input type="text"/>	
Temperature	<input type="text"/>	
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 checked="" 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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EAB) (1725)

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (12)

Data signed: (b) (4) 26 Mar 2021 00:56:18

Generated On: 09 Jun 2021 14:47:42

	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 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 14 Jan 2021

Form: Symptom Log (12)

Data signed: (b) (4) 26 Mar 2021 00:56:18

Generated On: 09 Jun 2021 14:47:42

Nasal Congestion	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" 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 14 Jan 2021

Form: Symptom Log (13)

Data signed: (b) (4) 26 Mar 2021 00:56:18

Generated On: 09 Jun 2021 14:47:42

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 14 Jan 2021

Form: Symptom Log (13)

Data signed: (b) (4) 26 Mar 2021 00:56:18

Generated On: 09 Jun 2021 14:47:42

	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	
---------------	--

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

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

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

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

Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input checked="" 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 checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (13)

Data signed: (b) (4) 26 Mar 2021 00:56:18

Generated On: 09 Jun 2021 14:47:42

	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 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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EAB) (1725)

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (13)

Data signed: (b) (4) 26 Mar 2021 00:56:18

Generated On: 09 Jun 2021 14:47:42

Nasal Congestion	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" 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 14 Jan 2021

Form: Symptom Log (14)

Data signed: (b) (4) 26 Mar 2021 00:56:18

Generated On: 09 Jun 2021 14:47:42

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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Form: Symptom Log (14)

Data signed: (b) (4) 26 Mar 2021 00:56:18

Generated On: 09 Jun 2021 14:47:42

	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	
---------------	--

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

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

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

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

Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input checked="" 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 checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>

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Form: Symptom Log (14)

Data signed: (b) (4) 26 Mar 2021 00:56:18

Generated On: 09 Jun 2021 14:47:42

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

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Form: Symptom Log (14)

Data signed: (b) (4) 26 Mar 2021 00:56:18

Generated On: 09 Jun 2021 14:47:42

Nasal Congestion	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" 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 14 Jan 2021

Form: Symptom Log (15)

Data signed: (b) (4) 26 Mar 2021 00:56:18

Generated On: 09 Jun 2021 14:47:42

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 14 Jan 2021

Form: Symptom Log (15)

Data signed: (b) (4) 26 Mar 2021 00:56:18

Generated On: 09 Jun 2021 14:47:42

	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	<input type="text"/>	
O2 Saturation Units	<input type="text"/>	
Temperature	<input type="text"/>	
Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input checked="" 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 checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>

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Form: Symptom Log (15)

Data signed: (b) (4) 26 Mar 2021 00:56:18

Generated On: 09 Jun 2021 14:47:42

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

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Form: Symptom Log (15)

Data signed: (b) (4) 26 Mar 2021 00:56:18

Generated On: 09 Jun 2021 14:47:42

Nasal Congestion	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" 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 14 Jan 2021

Form: Symptom Log (16)

Data signed: (b) (4) 26 Mar 2021 00:56:18

Generated On: 09 Jun 2021 14:47:42

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 14 Jan 2021

Form: Symptom Log (16)

Data signed: (b) (4) 26 Mar 2021 00:56:18

Generated On: 09 Jun 2021 14:47:42

	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	
---------------	--

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

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

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 14 Jan 2021

Form: Symptom Log (16)

Data signed: (b) (4) 26 Mar 2021 00:56:18

Generated On: 09 Jun 2021 14:47:42

	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 14 Jan 2021

Form: Symptom Log (16)

Data signed: (b) (4) 26 Mar 2021 00:56:18

Generated On: 09 Jun 2021 14:47:42

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 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 14 Jan 2021

Form: Symptom Log (17)

Data signed: (b) (4) 26 Mar 2021 00:56:18

Generated On: 09 Jun 2021 14:47:42

Symptom Day

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

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (17)

Data signed: (b) (4) 26 Mar 2021 00:56:18

Generated On: 09 Jun 2021 14:47:42

	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	97 %	
O2 Saturation Units	%	
Temperature	98.1 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input 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		388 of 2628
EAB) (1725)		

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (17)

Data signed: (b) (4) 26 Mar 2021 00:56:18

Generated On: 09 Jun 2021 14:47:42

	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"/>

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (17)

Data signed: (b) (4) 26 Mar 2021 00:56:18

Generated On: 09 Jun 2021 14:47:42

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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (18)

Data signed: (b) (4) 26 Mar 2021 00:56:18

Generated On: 09 Jun 2021 14:47:42

Symptom Day

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

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (18)

Data signed: (b) (4) 26 Mar 2021 00:56:18

Generated On: 09 Jun 2021 14:47:42

	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	97.9 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
PRODUCTION RELEASE (v12.003 EAB) (1725)	392 of 2628	

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (18)

Data signed: (b) (4) 26 Mar 2021 00:56:18

Generated On: 09 Jun 2021 14:47:42

	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"/>

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (18)

Data signed: (b) (4) 26 Mar 2021 00:56:18

Generated On: 09 Jun 2021 14:47:42

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 ☐

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (19)

Data signed: (b) (4) 26 Mar 2021 00:56:18

Generated On: 09 Jun 2021 14:47:42

Symptom Day

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

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (19)

Data signed: (b) (4) 26 Mar 2021 00:56:18

Generated On: 09 Jun 2021 14:47:42

	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	98 %	
O2 Saturation Units	%	
Temperature	97.7 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
PRODUCTION RELEASE (v12.003 EAB) (1725)	396 of 2628	

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (19)

Data signed: (b) (4) 26 Mar 2021 00:56:18

Generated On: 09 Jun 2021 14:47:42

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

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (19)

Data signed: (b) (4) 26 Mar 2021 00:56:18

Generated On: 09 Jun 2021 14:47:42

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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (21)

Data signed: (b) (4) 26 Mar 2021 00:56:18

Generated On: 09 Jun 2021 14:47:42

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input 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 14 Jan 2021

Form: Symptom Log (21)

Data signed: (b) (4) 26 Mar 2021 00:56:18

Generated On: 09 Jun 2021 14:47:42

	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	
Assessment Not Done	
O2 Saturation	
O2 Saturation Units	
Temperature	

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

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

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

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

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (21)

Data signed: (b) (4) 26 Mar 2021 00:56:18

Generated On: 09 Jun 2021 14:47:42

	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"/>

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (21)

Data signed: (b) (4) 26 Mar 2021 00:56:18

Generated On: 09 Jun 2021 14:47:42

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 14 Jan 2021

Form: COVID Diagnostic Test

Data signed: (b) (4) 26 Mar 2021 00:56:18

Generated On: 09 Jun 2021 14:47:42

Date of Visit	15 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 type="radio"/> No <input checked="" type="radio"/>
Date of Test	15 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)	0

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 26 Mar 2021 00:56:18

Generated On: 09 Jun 2021 14:47:42

[Generate Next COVID-19 Assessment](#)

Yes ☒

No ☐

US3012171

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 08 Apr 2021 14:53:55

Generated On: 09 Jun 2021 14:47:42

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	17 JAN 2021
Day 5	No	
Day 7	NA (COVID-19 Negative)	
Day 9	NA (COVID-19 Negative)	
Day 14	NA (COVID-19 Negative)	
Day 21	NA (COVID-19 Negative)	
Day 28	NA (COVID-19 Negative)	

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Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 26 Mar 2021 00:56:19

Generated On: 09 Jun 2021 14:47:42

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

US3012171

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 26 Mar 2021 00:56:19

Generated On: 09 Jun 2021 14:47:42

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	15 JAN 2021
Time of assessment (00:00-23:59)	15:10 (24 HR)
Vital Signs Date and Time (derived)	15 JAN 2021 15:10
Height (xxx.x)	67 in
Weight (xxx.x)	241.6 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)	92 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3012171

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Mar 2021 00:56:19

Generated On: 09 Jun 2021 14:47:42

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

15 JAN 2021

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

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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 00:56:19

Generated On: 09 Jun 2021 14:47:42

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

15 JAN 2021

US3012171

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

Form: Visit Date

Data signed: (b) (4) 26 Mar 2021 00:56:19

Generated On: 09 Jun 2021 14:47:42

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

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

Form: Unblinding

Data signed: (b) (4) 26 Mar 2021 00:56:19

Generated On: 09 Jun 2021 14:47:42

Date of updated informed consent (dd MMM yyyy) 11 MAR 2021

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

Was the participant unblinded? Yes ☒ No ☐

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

Date of unblinding (dd MMM yyyy) 11 MAR 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

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

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

Will participant receive mRNA-1273? Yes ☐ No ☒

Placebo Only Flag _____
Continuing with mRNA-1273 _____

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Mar 2021 00:56:19

Generated On: 09 Jun 2021 14:47:42

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

11 MAR 2021

Collection time (00:00-23:59)

11:44 (24 HR)

Collection date and time (derived)

11 MAR 2021 11:44

US3012171

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 26 Mar 2021 00:56:19

Generated On: 09 Jun 2021 14:47:42

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	11 MAR 2021
Collection time (00:00 - 23:59)	11:38
Collection Date and Time (derived)	11 MAR 2021 11:38

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Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 18 Mar 2021 23:04:48

Generated On: 09 Jun 2021 14:47:42

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 15 Apr 2021 16:35:54

Generated On: 09 Jun 2021 14:47:42

AEID	USA-US006-2021-MRNA-1273-P30 1000007
Adverse event	URINARY TRACT INFECTION
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	12 MAR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	13 APR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	12 MAR 2021
Hospital Discharge Date (dd MMM yyyy)	17 MAR 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 15 Apr 2021 16:35:54

Generated On: 09 Jun 2021 14:47:42

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	PT REPORTED TO ER ON 12-MAR-2021 DUE TO SEVERE PAIN IN ABDOMEN. DIAGNOSED WITH URINARY TRACT INFECTION AND BLADDER INFECTION.
Serious Adverse Event Derived (CSA Programming Field Only)	1
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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 15 Apr 2021 16:35:54

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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 (2)

Data signed: (b) (4) 15 Apr 2021 16:35:54

Generated On: 09 Jun 2021 14:47:42

AEID	USA-US006-2021-MRNA-1273-P30 1000007
Adverse event	LEUKOCYTOSIS
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	12 MAR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	13 APR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	12 MAR 2021
Hospital Discharge Date (dd MMM yyyy)	17 MAR 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 15 Apr 2021 16:35:54

Generated On: 09 Jun 2021 14:47:42

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	

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 15 Apr 2021 16:35:54

Generated On: 09 Jun 2021 14:47:42

PT REPORTED TO ER ON
12-MAR-2021 DUE TO SEVERE
PAIN IN ABDOMEN.
DIAGNOSED WITH URINARY
TRACT INFECTION AND
BLADDER INFECTION. PT DUE
TO BE DISCHARGED
16-MAR-2021.

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

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 15 Apr 2021 16:35:54

Generated On: 09 Jun 2021 14:47:42

AEID	USA-US006-2021-MRNA-1273-P30 1000007
Adverse event	EPIDIDYMITIS
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	12 MAR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	13 APR 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 checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	12 MAR 2021
Hospital Discharge Date (dd MMM yyyy)	17 MAR 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 15 Apr 2021 16:35:54

Generated On: 09 Jun 2021 14:47:42

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	THIS DX WAS LISTED ON THE HOSPITAL MEDICAL RECORDS ALONG WITH UTI AND LEUKOCYTOSIS.
Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0
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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 26 Mar 2021 00:56:18

Generated On: 09 Jun 2021 14:47:42

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 22:33:31

Generated On: 09 Jun 2021 14:47:42

Name of Medication SUPER BETA PROSTATE

Prophylaxis Yes ☐
No ☒

Indication NUTRITIONAL SUPPLEMENT

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 16 Apr 2021 22:33:31

Generated On: 09 Jun 2021 14:47:42

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	09 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	18 MAR 2021	
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 16 Apr 2021 22:33:31

Generated On: 09 Jun 2021 14:47:42

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒
No ☐

Indication INFLUENZA PREVENTION

Dose per administration .5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 16 Apr 2021 22:33:31

Generated On: 09 Jun 2021 14:47:42

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		27 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		27 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 16 Apr 2021 22:33:31

Generated On: 09 Jun 2021 14:47:42

Name of Medication FLOMAX

Prophylaxis Yes ☐
No ☒

Indication URINARY TRACT INFECTION
(AE #1)

Dose per administration 0.4

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 16 Apr 2021 22:33:31

Generated On: 09 Jun 2021 14:47:42

	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)		12 MAR 2021
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 16 Apr 2021 22:33:31

Generated On: 09 Jun 2021 14:47:42

Name of Medication AMOXICILLIN CLAVULANATE

Prophylaxis Yes ☐
No ☒

Indication UTI (AE #1)

Dose per administration 875

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 22:33:31

Generated On: 09 Jun 2021 14:47:42

	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)	12 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)		13 APR 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 (5)

Data signed: (b) (4) 16 Apr 2021 22:33:31

Generated On: 09 Jun 2021 14:47:42

Name of Medication DOCUSATE (COLACE)

Prophylaxis Yes ☐
No ☒

Indication EPIDIDYMITIS

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 16 Apr 2021 22:33:31

Generated On: 09 Jun 2021 14:47:42

	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)	12 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) 21 MAR 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 22:33:31

Generated On: 09 Jun 2021 14:47:42

Name of Medication ACETAMINOPHEN-HYDROCODONE

Prophylaxis Yes ☐
No ☒

Indication PAIN DUE TO UTI, LEUKOCYTOSIS

Dose per administration 5/325

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 16 Apr 2021 22:33:31

Generated On: 09 Jun 2021 14:47:42

	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)	12 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)	21 MAR 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	4	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3012171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 16 Apr 2021 22:33:31

Generated On: 09 Jun 2021 14:47:42

Name of Medication GLIPIZIDE

Prophylaxis Yes ☐
No ☒

Indication T2DM

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3012171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 16 Apr 2021 22:33:31

Generated On: 09 Jun 2021 14:47:42

	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)	12 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3012171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 16 Apr 2021 22:33:31

Generated On: 09 Jun 2021 14:47:42

Name of Medication	METFORMIN
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	T2DM
Dose per administration	500
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input type="radio"/> twice daily <input checked="" type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3012171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 16 Apr 2021 22:33:31

Generated On: 09 Jun 2021 14:47:42

	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)	12 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3012171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 16 Apr 2021 22:33:31

Generated On: 09 Jun 2021 14:47:42

Name of Medication NOVOLOG (INSULIN)

Prophylaxis Yes ☐
No ☒

Indication T2DM

Dose per administration LOW DOSE SLIDING SCALE

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

If dose unit is Other, specify LOW DOSE SLIDING SCALE

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3012171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 16 Apr 2021 22:33:31

Generated On: 09 Jun 2021 14:47:42

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	12 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	16 MAR 2021	
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3012171

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 26 Mar 2021 00:56:18

Generated On: 09 Jun 2021 14:47:42

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3012171

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 14:47:42

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 ☐

US3012171

Folder: SAE USA-US006-2021-MRNA-1273-P301000007

Form: Safety Report Form

Data signed: (b) (4) 15 Apr 2021 16:35:55

Generated On: 09 Jun 2021 14:47:42

SAEID	USA-US006-2021-MRNA-1273-P301000007
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	6

US3012171

Folder: SAE USA-US006-2021-MRNA-1273-P301000007

Form: Safety Report Form (1)

Data signed: (b) (4) 15 Apr 2021 16:35:55

Generated On: 09 Jun 2021 14:47:42

SAEID	USA-US006-2021-MRNA-1273-P301000007
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	6
Date of submission (Pre-filled from custom function)	16/MAR/2021 10:53
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

US3012171

Folder: SAE USA-US006-2021-MRNA-1273-P301000007

Form: Safety Report Form (2)

Data signed: (b) (4) 15 Apr 2021 16:35:55

Generated On: 09 Jun 2021 14:47:42

SAEID	USA-US006-2021-MRNA-1273-P301000007
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	6
Date of submission (Pre-filled from custom function)	25/MAR/2021 07:42
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

US3012171

Folder: SAE USA-US006-2021-MRNA-1273-P301000007

Form: Safety Report Form (3)

Data signed: (b) (4) 15 Apr 2021 16:35:55

Generated On: 09 Jun 2021 14:47:42

SAEID	USA-US006-2021-MRNA-1273-P301000007
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	6
Date of submission (Pre-filled from custom function)	29/MAR/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

US3012171

Folder: SAE USA-US006-2021-MRNA-1273-P301000007

Form: Safety Report Form (4)

Data signed: (b) (4) 15 Apr 2021 16:35:55

Generated On: 09 Jun 2021 14:47:42

SAEID	USA-US006-2021-MRNA-1273-P301000007
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	6
Date of submission (Pre-filled from custom function)	09/APR/2021 09:39
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

US3012171

Folder: SAE USA-US006-2021-MRNA-1273-P301000007

Form: Safety Report Form (5)

Data signed: (b) (4) 15 Apr 2021 16:35:55

Generated On: 09 Jun 2021 14:47:42

SAEID	USA-US006-2021-MRNA-1273-P301000007
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	6
Date of submission (Pre-filled from custom function)	13/APR/2021 10:29
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

US3012171

Folder: SAE USA-US006-2021-MRNA-1273-P301000007

Form: Safety Report Form (6)

Data signed: (b) (4) 15 Apr 2021 16:35:55

Generated On: 09 Jun 2021 14:47:42

SAEID	USA-US006-2021-MRNA-1273-P301000007
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	6
Date of submission (Pre-filled from custom function)	14/APR/2021 07:53
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

US3012171 (Prod: Benchmark Research-Austin)

US3012171

Form: Participant Creation

Generated On: 09 Jun 2021 14:47:42

[Participant ID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 13:16:03
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'US3012171'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	18 Aug 2020 19:19:44

US3012171

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 14:47:42

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:45:00
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered 'Yes (Y)'	Jennifer Leyva (b) (4)	18 Aug 2020 21:16:47

US3012171

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 14:47:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:45:00
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered '18 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	18 Aug 2020 19:19:45

US3012171

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 14:47:42

[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 11:45:00
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered 'Clinic (Clinic)'	Jennifer Leyva (b) (4)	18 Aug 2020 21:16:47

US3012171

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 14:47:42

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:45:00
User entered 'SCRN'	System	18 Aug 2020 21:16:47

US3012171

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:47:42

[Date of Birth \(MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:45:00
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered (b) (6) 1956'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	18 Aug 2020 19:19:46

US3012171

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:47:42

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:45:00
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered '64'	Jennifer Leyva (b) (4)	18 Aug 2020 21:16:55

US3012171

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:47:42

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:45:00
User entered 'YEARS'	System	18 Aug 2020 21:16:55

US3012171

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:47:42

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:45:00
User entered '64'	System	18 Aug 2020 21:17:04

US3012171

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:47:42

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:45:00
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered 'Male (M)'	Jennifer Leyva (b) (4)	18 Aug 2020 21:16:55

US3012171

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:47:42

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:45:00
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Jennifer Leyva (b) (4)	18 Aug 2020 21:16:55

US3012171

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:47:42

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:45:00
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered 'I'	Jennifer Leyva (b) (4)	18 Aug 2020 21:16:55

US3012171

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:47:42

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:45:00
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered '0'	Jennifer Leyva (b) (4)	18 Aug 2020 21:16:55

US3012171

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:47:42

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:45:00
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered '0'	Jennifer Leyva (b) (4)	18 Aug 2020 21:16:55

US3012171

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:47:42

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:45:00
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered '0'	Jennifer Leyva (b) (4)	18 Aug 2020 21:16:55

US3012171

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:47:42

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:45:00
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered '0'	Jennifer Leyva (b) (4)	18 Aug 2020 21:16:55

US3012171

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:47:42

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:45:00
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered '0'	Jennifer Leyva (b) (4)	18 Aug 2020 21:16:55

US3012171

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:47:42

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:45:00
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered empty.	Jennifer Leyva (b) (4)	18 Aug 2020 21:16:55

US3012171

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:47:42

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:45:00
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered '0'	Jennifer Leyva (b) (4)	18 Aug 2020 21:16:55

US3012171

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:47:42

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:45:00
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered '0'	Jennifer Leyva (b) (4)	18 Aug 2020 21:16:55

US3012171

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:47:42

[Date of Informed Consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:45:00
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered '18 Aug 2020'	Jennifer Leyva (b) (4)	18 Aug 2020 21:17:04

US3012171

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:47:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:45:00
User entered 'Aug 2020'	System	18 Aug 2020 21:17:04

US3012171

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:47:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:45:00
User entered '2020'	System	18 Aug 2020 21:17:04

US3012171

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:47:42

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:45:00
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered 'Amendment 2 (2)'	Jennifer Leyva (b) (4)	18 Aug 2020 21:17:04

US3012171

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:47:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:45:00
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered 'Yes (Y)'	Jennifer Leyva (b) (4)	18 Aug 2020 21:17:04

US3012171

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:47:42

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:45:00
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered empty.	Jennifer Leyva (b) (4)	18 Aug 2020 21:17:04

US3012171

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:47:42

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:45:00
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered empty.	Jennifer Leyva (b) (4)	18 Aug 2020 21:17:04

US3012171

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:47:42

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:45:00
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered 'No (N)'	Jennifer Leyva (b) (4)	18 Aug 2020 21:17:04

US3012171

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:47:42

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:45:00
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	18 Aug 2020 19:19:45

US3012171

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:47:42

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:45:00
User entered 'I'	System	18 Aug 2020 21:17:08

US3012171

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 14:47:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:45:00
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered 'Yes (Y)'	Jennifer Leyva (b) (4)	18 Aug 2020 21:17:08

US3012171

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 14:47:42

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:45:00
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered 'Yes (Y)'	Jennifer Leyva (b) (4)	19 Aug 2020 15:22:18

US3012171

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:47:42

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:45:00
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4)	19 Aug 2020 15:24:24
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	19 Aug 2020 15:24:24
Data point term sent to Coder	System	19 Aug 2020 15:23:32
User entered 'seasonal allergies, unspecified'	Jennifer Leyva (b) (4)	19 Aug 2020 15:22:49

US3012171

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:47:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:45:00
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered 'UN UNK 1960'	Jennifer Leyva (b) (4)	19 Aug 2020 15:22:49

US3012171

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:47:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:45:00
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered '0'	Jennifer Leyva (b) (4)	19 Aug 2020 15:22:49

US3012171

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:47:42

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:45:00
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered 'Yes (Y)'	Jennifer Leyva (b) (4)	19 Aug 2020 15:22:49

US3012171

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:47:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:45:00
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered empty.	Jennifer Leyva (b) (4)	19 Aug 2020 15:22:49

US3012171

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:47:42

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:45:00
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered '0'	Jennifer Leyva (b) (4)	19 Aug 2020 15:22:49

US3012171

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:47:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:45:00
User entered 'Jan 1960'	System	19 Aug 2020 15:22:49

US3012171

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:47:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:45:00
User entered '1960'	System	19 Aug 2020 15:22:49

US3012171

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:47:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:45:00
User entered empty.	System	19 Aug 2020 15:22:49

US3012171

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:47:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:45:00
User entered empty.	System	19 Aug 2020 15:22:49

US3012171

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:47:42

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:45:00
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Food allergy, LLT: Fruit allergy - version MedDRA\\23.0.	Coder Import (b) (4)	19 Aug 2020 21:08:11
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	19 Aug 2020 21:08:11
Data point term sent to Coder	System	19 Aug 2020 15:24:35
User entered 'allergy to citrus'	Jennifer Leyva (b) (4)	19 Aug 2020 15:23:37

US3012171

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:47:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:45:00
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered 'UN UNK 1970'	Jennifer Leyva (b) (4)	19 Aug 2020 15:23:37

US3012171

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:47:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:45:00
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered '0'	Jennifer Leyva (b) (4)	19 Aug 2020 15:23:37

US3012171

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:47:42

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:45:00
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered 'Yes (Y)'	Jennifer Leyva (b) (4)	19 Aug 2020 15:23:37

US3012171

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:47:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:45:00
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered empty.	Jennifer Leyva (b) (4)	19 Aug 2020 15:23:37

US3012171

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:47:42

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:45:00
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered '0'	Jennifer Leyva (b) (4)	19 Aug 2020 15:23:37

US3012171

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:47:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:45:00
User entered 'Jan 1970'	System	19 Aug 2020 15:23:37

US3012171

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:47:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:45:00
User entered '1970'	System	19 Aug 2020 15:23:37

US3012171

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:47:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:45:00
User entered empty.	System	19 Aug 2020 15:23:37

US3012171

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:47:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:45:00
User entered empty.	System	19 Aug 2020 15:23:37

US3012171

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:47:42

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:45:00
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Appetite and general nutritional disorders, HLT: General nutritional disorders NEC, PT: Obesity, LLT: Obesity - version MedDRA\\23.0.	Coder Import (b) (4)	19 Aug 2020 15:25:30
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	19 Aug 2020 15:25:30
Data point term sent to Coder	System	19 Aug 2020 15:24:34
User entered 'obesity'	Jennifer Leyva (b) (4)	19 Aug 2020 15:23:48

US3012171

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:47:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:45:00
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered 'UN UNK 2016'	Jennifer Leyva (b) (4)	19 Aug 2020 15:23:48

US3012171

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:47:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:45:00
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered '0'	Jennifer Leyva (b) (4)	19 Aug 2020 15:23:48

US3012171

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:47:42

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:45:00
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered 'Yes (Y)'	Jennifer Leyva (b) (4)	19 Aug 2020 15:23:48

US3012171

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:47:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:45:00
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered empty.	Jennifer Leyva (b) (4)	19 Aug 2020 15:23:48

US3012171

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:47:42

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:45:00
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered '0'	Jennifer Leyva (b) (4)	19 Aug 2020 15:23:48

US3012171

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:47:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:45:00
User entered 'Jan 2016'	System	19 Aug 2020 15:23:48

US3012171

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:47:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:45:00
User entered '2016'	System	19 Aug 2020 15:23:48

US3012171

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:47:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:45:00
User entered empty.	System	19 Aug 2020 15:23:48

US3012171

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:47:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:45:00
User entered empty.	System	19 Aug 2020 15:23:48

US3012171

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:47:42

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:45:00
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User closed query 'Per DM CLR: Please review and please note that there is no listed treatment for this condition and treatment is expected. Please review and update to record the corresponding treatment if applicable. Otherwise, clarify reason why no treatment is needed. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Oct 2020 07:29:31
Query 'Per DM CLR: Please review and please note that there is no listed treatment for this condition and treatment is expected. Please review and update to record the corresponding treatment if applicable. Otherwise, clarify reason why no treatment is needed. ' answered with 'Correct as entered. Per pt, condition is treated with diet and exercise.' (Site from DM).	Jennifer Leyva (b) (4) (b) (4)	30 Sep 2020 13:18:56
User opened query 'Per DM CLR: Please review and please note that there is no listed treatment for this condition and treatment is expected. Please review and update to record the corresponding treatment if applicable. Otherwise, clarify reason why no treatment is needed. ' (Site from DM).	(b) (4), (b) (6)	01 Sep 2020 09:14:46
User coded data point as SOC: Metabolism and nutrition disorders, HLG: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 2 diabetes mellitus, LLT: Type II diabetes mellitus - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 15:25:31
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 15:25:31
Data point term sent to Coder	System	19 Aug 2020 15:24:37
User entered 'diabetes, type ii'	Jennifer Leyva (b) (4) (b) (4)	19 Aug 2020 15:24:36

US3012171

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:47:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:45:00
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered 'UN UNK 2018'	Jennifer Leyva (b) (4)	19 Aug 2020 15:24:36

US3012171

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:47:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:45:00
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered '0'	Jennifer Leyva (b) (4)	19 Aug 2020 15:24:36

US3012171

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:47:42

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:45:00
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered 'Yes (Y)'	Jennifer Leyva (b) (4)	19 Aug 2020 15:24:36

US3012171

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:47:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:45:00
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered empty.	Jennifer Leyva (b) (4)	19 Aug 2020 15:24:36

US3012171

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:47:42

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:45:00
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered '0'	Jennifer Leyva (b) (4)	19 Aug 2020 15:24:36

US3012171

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:47:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:45:00
User entered 'Jan 2018'	System	19 Aug 2020 15:24:36

US3012171

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:47:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:45:00
User entered '2018'	System	19 Aug 2020 15:24:36

US3012171

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:47:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:45:00
User entered empty.	System	19 Aug 2020 15:24:36

US3012171

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:47:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:45:00
User entered empty.	System	19 Aug 2020 15:24:36

US3012171

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:47:42

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:45:00
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User coded data point as SOC: Renal and urinary disorders, HLGT: Bladder and bladder neck disorders (excl calculi), HLT: Myoneurogenic bladder disorders, PT: Hypertonic bladder, LLT: Overactive bladder - version MedDRA\\23.0.	Coder Import (b) (4)	19 Aug 2020 15:27:26
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	19 Aug 2020 15:27:26
Data point term sent to Coder	System	19 Aug 2020 15:25:40
User entered 'overactive bladder'	Jennifer Leyva (b) (4)	19 Aug 2020 15:25:06

US3012171

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:47:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:45:00
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered 'UN UNK 2017'	Jennifer Leyva (b) (4)	19 Aug 2020 15:25:06

US3012171

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:47:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:45:00
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered '0'	Jennifer Leyva (b) (4)	19 Aug 2020 15:25:06

US3012171

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:47:42

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:45:00
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered 'Yes (Y)'	Jennifer Leyva (b) (4)	19 Aug 2020 15:25:06

US3012171

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:47:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:45:00
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered empty.	Jennifer Leyva (b) (4)	19 Aug 2020 15:25:06

US3012171

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:47:42

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:45:00
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered '0'	Jennifer Leyva (b) (4)	19 Aug 2020 15:25:06

US3012171

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:47:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:45:00
User entered 'Jan 2017'	System	19 Aug 2020 15:25:06

US3012171

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:47:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:45:00
User entered '2017'	System	19 Aug 2020 15:25:06

US3012171

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:47:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:45:00
User entered empty.	System	19 Aug 2020 15:25:06

US3012171

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:47:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:45:00
User entered empty.	System	19 Aug 2020 15:25:06

US3012171

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:47:42

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:45:00
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Finger osteoarthritis - version MedDRA\\23.0.	Coder Import (b) (4)	14 Sep 2020 13:35:42
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	14 Sep 2020 13:35:42
Data point term sent to Coder	System	19 Aug 2020 15:25:41
User entered 'osteoarthritis, bilateral fingers'	Jennifer Leyva (b) (4)	19 Aug 2020 15:25:20

US3012171

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:47:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:45:00
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered 'UN UNK 1973'	Jennifer Leyva (b) (4)	19 Aug 2020 15:25:20

US3012171

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:47:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:45:00
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered '0'	Jennifer Leyva (b) (4)	19 Aug 2020 15:25:20

US3012171

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:47:42

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:45:00
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered 'Yes (Y)'	Jennifer Leyva (b) (4)	19 Aug 2020 15:25:20

US3012171

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:47:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:45:00
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered empty.	Jennifer Leyva (b) (4)	19 Aug 2020 15:25:20

US3012171

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:47:42

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:45:00
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered '0'	Jennifer Leyva (b) (4)	19 Aug 2020 15:25:20

US3012171

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:47:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:45:00
User entered 'Jan 1973'	System	19 Aug 2020 15:25:20

US3012171

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:47:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:45:00
User entered '1973'	System	19 Aug 2020 15:25:20

US3012171

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:47:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:45:00
User entered empty.	System	19 Aug 2020 15:25:20

US3012171

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:47:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:45:00
User entered empty.	System	19 Aug 2020 15:25:20

US3012171

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:47:42

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:45:00
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Back pain, LLT: Lumbar pain - version MedDRA\\23.0.	Coder Import (b) (4)	19 Aug 2020 15:27:28
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	19 Aug 2020 15:27:28
Data point term sent to Coder	System	19 Aug 2020 15:26:45
User entered 'back pain, lumbar'	Jennifer Leyva (b) (4)	19 Aug 2020 15:26:16

US3012171

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:47:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:45:00
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered '12 Sep 2018'	Jennifer Leyva (b) (4)	19 Aug 2020 15:26:16

US3012171

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:47:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:45:00
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered '0'	Jennifer Leyva (b) (4)	19 Aug 2020 15:26:16

US3012171

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:47:42

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:45:00
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered 'No (N)'	Jennifer Leyva (b) (4)	19 Aug 2020 15:26:16

US3012171

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:47:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:45:00
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered 'UN Nov 2018'	Jennifer Leyva (b) (4)	19 Aug 2020 15:26:16

US3012171

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:47:42

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:45:00
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered '0'	Jennifer Leyva (b) (4)	19 Aug 2020 15:26:16

US3012171

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:47:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:45:00
User entered 'Sep 2018'	System	19 Aug 2020 15:26:16

US3012171

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:47:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:45:00
User entered '2018'	System	19 Aug 2020 15:26:16

US3012171

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:47:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:45:00
User entered 'Nov 2018'	System	19 Aug 2020 15:26:16

US3012171

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:47:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:45:00
User entered '2018'	System	19 Aug 2020 15:26:16

US3012171

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:47:42

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:45:00
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered 'Yes (Y)'	Jennifer Leyva (b) (4)	19 Aug 2020 15:27:34

US3012171

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:47:42

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:45:00
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered '18 Aug 2020'	Jennifer Leyva (b) (4)	19 Aug 2020 15:27:34

US3012171

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:47:42

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:45:00
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered '14:26'	Jennifer Leyva (b) (4)	19 Aug 2020 15:27:34

US3012171

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:47:42

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:45:00
User entered '18 Aug 2020 14:26'	System	19 Aug 2020 15:27:34

US3012171

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:47:42

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:45:00
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered '66.5' in	(b) (4) Jennifer Leyva (b) (4)	19 Aug 2020 15:27:34
DataPoint set to visible.	(b) (4) System	18 Aug 2020 21:17:08

US3012171

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:47:42

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:45:00
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered '245.0' lb	Jennifer Leyva (b) (4)	19 Aug 2020 15:27:34
DataPoint set to visible.	System	18 Aug 2020 21:17:08

US3012171

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:47:42

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:45:00
Amendment Manager: User entered '39.03307'	System	17 Sep 2020 00:12:48
User entered '39.0'	System	19 Aug 2020 15:27:34
DataPoint set to visible.	System	18 Aug 2020 21:17:08

US3012171

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:47:42

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:45:00
User entered 'kg/m2'	System	19 Aug 2020 15:27:34
DataPoint set to visible.	System	18 Aug 2020 21:17:08

US3012171

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:47:42

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:45:00
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered missing code ND - Not Done.	Jennifer Leyva (b) (4)	19 Aug 2020 15:27:34

US3012171

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:47:42

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:45:00
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	20 Aug 2020 17:37:30
Query 'Data is required. Please provide.' answered with 'ND' (Site from System).	Jennifer Leyva (b) (4)	19 Aug 2020 15:27:43
User opened query 'Data is required. Please provide.' (Site from System).	System	19 Aug 2020 15:27:34
User entered empty.	Jennifer Leyva (b) (4)	19 Aug 2020 15:27:34

US3012171

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:47:42

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:45:00
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered empty.	Jennifer Leyva (b) (4)	19 Aug 2020 15:27:34

US3012171

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:47:42

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:45:00
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered missing code ND - Not Done.	Jennifer Leyva (b) (4)	19 Aug 2020 15:27:34

US3012171

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:47:42

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:45:00
User entered 'bpm'	System	19 Aug 2020 15:27:34

US3012171

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:47:42

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:45:00
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered missing code ND - Not Done.	Jennifer Leyva (b) (4)	19 Aug 2020 15:27:34

US3012171

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:47:42

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:45:00
User entered 'breaths/min'	System	19 Aug 2020 15:27:34

US3012171

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:47:42

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:45:00
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered missing code ND - Not Done.	Jennifer Leyva (b) (4)	19 Aug 2020 15:27:34

US3012171

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:47:42

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:45:00
User entered 'mmHg'	System	19 Aug 2020 15:27:34

US3012171

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:47:42

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:45:00
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered missing code ND - Not Done.	Jennifer Leyva (b) (4)	19 Aug 2020 15:27:34

US3012171

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:47:42

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:45:00
User entered 'mmHg'	System	19 Aug 2020 15:27:34

US3012171

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:47:42

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:45:00

US3012171

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:47:42

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:45:00

US3012171

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 14:47:42

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:45:00
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered 'Yes (Y)'	Jennifer Leyva (b) (4)	19 Aug 2020 15:27:51

US3012171

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 14:47:42

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:45:00
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
Amendment Manager: Query closed during migrationSystem process because the edit check no longer exists in target version.	(b) (4)	30 Sep 2020 20:59:48
User opened query 'The Physical Examination Date isSystem prior to the Screening Visit Date. Please review and reconcile.' (Site from System).		15 Sep 2020 15:50:24
User entered '18 Aug 2020'	Jennifer Leyva (b) (4)	19 Aug 2020 15:27:51
	(b) (4)	

US3012171

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:47:42

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 11:45:00
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered 'No (N)'	Jennifer Leyva (b) (4)	19 Aug 2020 15:28:37

US3012171

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:47:42

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 11:45:00
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered 'No (N)'	Jennifer Leyva (b) (4)	19 Aug 2020 15:28:37

US3012171

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:47:42

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 11:45:00
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered 'No (N)'	Jennifer Leyva (b) (4)	19 Aug 2020 15:28:37

US3012171

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:47:42

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 11:45:00
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered 'No (N)'	Jennifer Leyva (b) (4)	19 Aug 2020 15:28:37

US3012171

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:47:42

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 11:45:00
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered 'No (N)'	Jennifer Leyva (b) (4)	19 Aug 2020 15:28:37

US3012171

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:47:42

[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 11:45:00
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered 'No (N)'	Jennifer Leyva (b) (4)	19 Aug 2020 15:28:37

US3012171

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:47:42

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 11:45:00
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered 'No (N)'	Jennifer Leyva (b) (4)	19 Aug 2020 15:28:37

US3012171

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:47:42

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 11:45:00
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered 'No (N)'	Jennifer Leyva (b) (4)	19 Aug 2020 15:28:37

US3012171

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:47:42

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 11:45:00
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered 'No (N)'	Jennifer Leyva (b) (4)	19 Aug 2020 15:28:37

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Folder: Screening

Form: Risk of Exposure

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Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:45:00
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered 'Yes (Y)'	Jennifer Leyva (b) (4)	19 Aug 2020 15:28:37

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Folder: Screening

Form: Risk of Exposure

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Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:45:00
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered 'No (N)'	Jennifer Leyva (b) (4)	19 Aug 2020 15:28:37

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Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:45:00
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered 'No (N)'	Jennifer Leyva (b) (4)	19 Aug 2020 15:28:37

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Folder: Screening

Form: Risk of Exposure

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[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:45:00
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered empty.	Jennifer Leyva (b) (4)	19 Aug 2020 15:28:37

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Folder: Screening

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No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:45:00
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered '0'	Jennifer Leyva (b) (4)	19 Aug 2020 15:28:37

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Folder: Screening

Form: Risk of Exposure

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[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:45:00
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered '0'	Jennifer Leyva (b) (4)	19 Aug 2020 15:28:37

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Folder: Screening

Form: Risk of Exposure

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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 11:45:00
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered '0'	Jennifer Leyva (b) (4)	19 Aug 2020 15:28:37

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Folder: Screening

Form: Risk of Exposure

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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 11:45:00
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered 'I'	Jennifer Leyva (b) (4)	19 Aug 2020 15:28:37

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Folder: Screening

Form: Risk of Exposure

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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 11:45:00
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered '0'	Jennifer Leyva (b) (4)	19 Aug 2020 15:28:37

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Folder: Screening

Form: Risk of Exposure

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Resides in a single family home (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:45:00
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered '0'	Jennifer Leyva (b) (4)	19 Aug 2020 15:28:37

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:47:42

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:45:00
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered '0'	Jennifer Leyva (b) (4)	19 Aug 2020 15:28:37

US3012171

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:47:42

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:45:00
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered empty.	Jennifer Leyva (b) (4)	19 Aug 2020 15:28:37

US3012171

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 14:47:42

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered 'Yes (Y)'	Jennifer Leyva (b) (4)	19 Aug 2020 15:28:48

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 14:47:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered '18 Aug 2020'	Jennifer Leyva (b) (4)	19 Aug 2020 15:28:48

US3012171

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 14:47:42

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered 'Clinic (Clinic)'	Jennifer Leyva (b) (4)	19 Aug 2020 15:28:48

US3012171

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 14:47:42

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User entered 'VISIT1'	System	19 Aug 2020 15:28:48

US3012171

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:47:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered '18 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	18 Aug 2020 20:44:13

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:47:42

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) System	21 Aug 2020 05:24:10
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 05:24:10
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	18 Aug 2020 20:44:13
User entered '144213' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	18 Aug 2020 20:44:13

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:47:42

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered '>=18 and <65 years and at risk (2)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	18 Aug 2020 20:44:13

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:47:42

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered 'No (N)'	Jennifer Leyva (b) (4)	19 Aug 2020 15:29:21

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:47:42

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered 'No (N)'	Jennifer Leyva (b) (4)	19 Aug 2020 15:29:21

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:47:42

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered 'No (N)'	Jennifer Leyva (b) (4)	19 Aug 2020 15:29:21

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:47:42

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered 'Yes (Y)'	Jennifer Leyva (b) (4)	19 Aug 2020 15:29:21

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:47:42

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered 'No (N)'	Jennifer Leyva (b) (4)	19 Aug 2020 15:29:21

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:47:42

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User closed query 'Per CDM: this field requires yes or no. Please complete. ' (Site from DM).	(b) (4)	30 Oct 2020 06:58:27
Query 'Per CDM: this field requires yes or no. Please complete. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 15:03:06
User entered 'No (N)'	Pamela Fidler (b) (4)	28 Oct 2020 15:03:02
User opened query 'Per CDM: this field requires yes or no. Please complete. ' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 12:52:35
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:35:10
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 01:22:53

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:47:42

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered missing code ND - Not Done.	Jennifer Leyva (b) (4)	19 Aug 2020 15:29:45

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:47:42

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered missing code ND - Not Done.	Jennifer Leyva (b) (4)	19 Aug 2020 15:29:45

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:47:42

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered missing code ND - Not Done.	Jennifer Leyva (b) (4)	19 Aug 2020 15:29:45

US3012171

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:47:42

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered missing code ND - Not Done.	(b) (4) Jennifer Leyva (b) (4)	19 Aug 2020 15:29:45

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:47:42

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User accepted default value 'Pre-Dose (PREDOSE)'	Jennifer Leyva (b) (4) (b) (4)	19 Aug 2020 15:29:45

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:47:42

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered 'Yes (Y)'	Jennifer Leyva (b) (4)	19 Aug 2020 15:29:45

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:47:42

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered '18 Aug 2020'	Jennifer Leyva (b) (4)	19 Aug 2020 15:29:45

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:47:42

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered '14:26'	Jennifer Leyva (b) (4)	19 Aug 2020 15:29:45

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:47:42

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User entered '18 Aug 2020 14:26'	System	19 Aug 2020 15:29:45

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:47:42

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	19 Aug 2020 15:30:06
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	19 Aug 2020 15:30:06
User entered '98.3' F reason for change: Data Entry Error	Jennifer Leyva (b) (4)	19 Aug 2020 15:30:06
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	19 Aug 2020 15:29:45
User entered empty.	System	19 Aug 2020 15:29:45
	Jennifer Leyva (b) (4)	19 Aug 2020 15:29:45
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:47:42

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered 'Oral (Oral)'	Jennifer Leyva (b) (4)	19 Aug 2020 15:29:45

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:47:42

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered empty.	Jennifer Leyva (b) (4)	19 Aug 2020 15:29:45

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:47:42

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered '98'	Jennifer Leyva (b) (4)	19 Aug 2020 15:29:45

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:47:42

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User entered 'bpm'	System	19 Aug 2020 15:29:45

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:47:42

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered '14'	Jennifer Leyva (b) (4)	19 Aug 2020 15:29:45

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:47:42

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User entered 'breaths/min'	System	19 Aug 2020 15:29:45

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:47:42

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered '111'	Jennifer Leyva (b) (4)	19 Aug 2020 15:29:45

US3012171

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:47:42

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User entered 'mmHg'	System	19 Aug 2020 15:29:45

US3012171

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:47:42

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered '69'	Jennifer Leyva (b) (4)	19 Aug 2020 15:29:45

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:47:42

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User entered 'mmHg'	System	19 Aug 2020 15:29:45

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:47:42

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered missing code ND - Not Done.	Jennifer Leyva (b) (4)	19 Aug 2020 15:29:45

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:47:42

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered missing code ND - Not Done.	Jennifer Leyva (b) (4)	19 Aug 2020 15:29:45

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:47:42

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User accepted default value 'Post-Dose (POSTDOSE)'	Jennifer Leyva (b) (4) (b) (4)	19 Aug 2020 15:30:25

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:47:42

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered 'Yes (Y)'	Jennifer Leyva (b) (4)	19 Aug 2020 15:30:25

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:47:42

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered '18 Aug 2020'	Jennifer Leyva (b) (4)	19 Aug 2020 15:30:25

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:47:42

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User closed query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	(b) (4)	
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'post-dose observation is 30 minutes' (Site from System).	(b) (4), (b) (6)	20 Aug 2020 06:41:17
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'post-dose observation is 30 minutes' (Site from System).	Jennifer Leyva (b) (4)	19 Aug 2020 15:30:36
User opened query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	(b) (4)	
User opened query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		19 Aug 2020 15:30:25
User entered '16:48'	Jennifer Leyva (b) (4)	19 Aug 2020 15:30:25
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:47:42

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User entered '18 Aug 2020 16:48'	System	19 Aug 2020 15:30:25

US3012171

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:47:42

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered '98.3' F	Jennifer Leyva (b) (4)	19 Aug 2020 15:30:25

US3012171

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:47:42

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered 'Oral (Oral)'	Jennifer Leyva (b) (4)	19 Aug 2020 15:30:25

US3012171

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:47:42

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered empty.	Jennifer Leyva (b) (4)	19 Aug 2020 15:30:25

US3012171

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:47:42

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered '88'	Jennifer Leyva (b) (4)	19 Aug 2020 15:30:25

US3012171

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:47:42

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User entered 'bpm'	System	19 Aug 2020 15:30:25

US3012171

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:47:42

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered '14'	Jennifer Leyva (b) (4)	19 Aug 2020 15:30:25

US3012171

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:47:42

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User entered 'breaths/min'	System	19 Aug 2020 15:30:25

US3012171

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:47:42

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered '118'	Jennifer Leyva (b) (4)	19 Aug 2020 15:30:25

US3012171

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:47:42

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User entered 'mmHg'	System	19 Aug 2020 15:30:25

US3012171

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:47:42

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered '82'	Jennifer Leyva (b) (4)	19 Aug 2020 15:30:25

US3012171

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:47:42

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User entered 'mmHg'	System	19 Aug 2020 15:30:25

US3012171

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 14:47:42

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered 'No (N)'	Jennifer Leyva (b) (4)	19 Aug 2020 15:30:43

US3012171

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 14:47:42

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered empty.	Jennifer Leyva (b) (4)	19 Aug 2020 15:30:43

US3012171

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:47:42

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered 'Yes (Y)'	Jennifer Leyva (b) (4)	18 Aug 2020 21:19:51

US3012171

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:47:42

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered empty.	Jennifer Leyva (b) (4)	18 Aug 2020 21:19:51

US3012171

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:47:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered empty.	Jennifer Leyva (b) (4)	18 Aug 2020 21:19:51

US3012171

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:47:42

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User entered 'MRNA-1273 OR PLACEBO'	System	18 Aug 2020 21:19:51

US3012171

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:47:42

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered '18 Aug 2020'	Jennifer Leyva (b) (4)	18 Aug 2020 21:19:51

US3012171

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:47:42

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered '16:06'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	18 Aug 2020 21:19:51

US3012171

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:47:42

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User entered '18 Aug 2020 16:06'	System	18 Aug 2020 21:19:51

US3012171

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:47:42

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered 'Left Arm (LEFT ARM)'	Jennifer Leyva (b) (4)	18 Aug 2020 21:19:51

US3012171

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:47:42

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User entered 'ONCE'	System	18 Aug 2020 21:19:51

US3012171

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:47:42

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User entered 'INTRAMUSCULAR'	System	18 Aug 2020 21:19:51

US3012171

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:47:42

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered 'Yes (Y)'	Jennifer Leyva (b) (4)	19 Aug 2020 15:31:10

US3012171

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:47:42

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered '18 Aug 2020'	Jennifer Leyva (b) (4)	19 Aug 2020 15:31:10

US3012171

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:47:42

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered '15:28'	Jennifer Leyva (b) (4)	19 Aug 2020 15:31:10

US3012171

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:47:42

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User entered '18 Aug 2020 15:28'	System	19 Aug 2020 15:31:10

US3012171

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 14:47:42

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered '18 Aug 2020'	Jennifer Leyva (b) (4)	19 Aug 2020 15:31:25

US3012171

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:47:42

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Jennifer Leyva (b) (4) (b) (4)	19 Aug 2020 15:31:25

US3012171

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:47:42

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered 'Yes (Y)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	19 Aug 2020 15:31:25

US3012171

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:47:42

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered '15:04'	Jennifer Leyva (b) (4)	19 Aug 2020 15:31:25

US3012171

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:47:42

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User entered '18 Aug 2020 15:04'	System	19 Aug 2020 15:31:25

US3012171

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:47:42

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Jennifer Leyva (b) (4) (b) (4)	19 Aug 2020 15:31:25

US3012171

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:47:42

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered 'No (N)'	Jennifer Leyva (b) (4)	19 Aug 2020 15:31:25

US3012171

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:47:42

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered empty.	Jennifer Leyva (b) (4)	19 Aug 2020 15:31:25

US3012171

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:47:42

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User entered empty.	System	19 Aug 2020 15:31:25

US3012171

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 14:47:42

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered 'Yes (Y)'	Jennifer Leyva (b) (4)	19 Aug 2020 15:31:28

US3012171

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 14:47:42

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User entered 'I'	System	19 Aug 2020 15:31:28

US3012171

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
Data entry locked.	System	18 Aug 2020 21:19:51
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	18 Aug 2020 21:19:51

US3012171

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:47:42

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-08-18T16:38:21', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: 'e86a3850-8383-48b6-9620-1ea9f6aa6e18'	System	18 Aug 2020 21:38:43
User entered 'Yes (Y)'	System	18 Aug 2020 21:38:43

US3012171

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:47:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-08-18T16:38:27', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: 'e86a3850-8383-48b6-9620-1ea9f6aa6e18'	System	18 Aug 2020 21:38:43
User entered '98.3'	System	18 Aug 2020 21:38:43

US3012171

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:47:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-08-18T16:38:31', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: 'e86a3850-8383-48b6-9620-1ea9f6aa6e18'	System	18 Aug 2020 21:38:43
User entered 'No (N)'	System	18 Aug 2020 21:38:43

US3012171

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:47:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-08-18T16:38:37', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: 'e86a3850-8383-48b6-9620-1ea9f6aa6e18'	System	18 Aug 2020 21:38:43
User entered '18 Aug 2020 16:38'	System	18 Aug 2020 21:38:43

US3012171

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:47:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
User entered '18 Aug 2020 16:26'	System	18 Aug 2020 21:19:51

US3012171

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:47:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
User entered '18 Aug 2020 18:56'	System	18 Aug 2020 21:19:51

US3012171

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
Data entry locked.	System	18 Aug 2020 21:19:51
User entered 'Day 1, after vaccination (at home)'	System	18 Aug 2020 21:19:51

US3012171

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:47:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-08-18T21:06:03', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: 'fc2cd3d9-f00f-4609-bcce-c2a4d4d1f062'	System	19 Aug 2020 02:06:26
User entered 'Yes (Y)'	System	19 Aug 2020 02:06:26

US3012171

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:47:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-08-18T21:06:13', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: 'fc2cd3d9-f00f-4609-bcce-c2a4d4d1f062'	System	19 Aug 2020 02:06:26
User entered '97.8'	System	19 Aug 2020 02:06:26

US3012171

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:47:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-08-18T21:06:17', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: 'fc2cd3d9-f00f-4609-bcce-c2a4d4d1f062'	System	19 Aug 2020 02:06:26
User entered 'No (N)'	System	19 Aug 2020 02:06:26

US3012171

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:47:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-08-18T21:06:23', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: 'fc2cd3d9-f00f-4609-bcce-c2a4d4d1f062'	System	19 Aug 2020 02:06:26
User entered '18 Aug 2020 21:06'	System	19 Aug 2020 02:06:26

US3012171

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:47:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
User entered '18 Aug 2020 19:51'	System	18 Aug 2020 21:19:51

US3012171

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:47:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
User entered '19 Aug 2020 11:59'	System	18 Aug 2020 21:19:51

US3012171

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
Data entry locked.	System	18 Aug 2020 21:19:51
User entered 'Day 2'	System	18 Aug 2020 21:19:51

US3012171

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:47:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-08-20T00:00:02', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '88fa8255-de86-4814-8d3e-635724880ef6'	System	20 Aug 2020 05:00:23
User entered 'Yes (Y)'	System	20 Aug 2020 05:00:23

US3012171

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:47:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-08-20T00:00:11', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '88fa8255-de86-4814-8d3e-635724880ef6'	System	20 Aug 2020 05:00:23
User entered '98.1'	System	20 Aug 2020 05:00:23

US3012171

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:47:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-08-20T00:00:14', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '88fa8255-de86-4814-8d3e-635724880ef6'	System	20 Aug 2020 05:00:23
User entered 'No (N)'	System	20 Aug 2020 05:00:23

US3012171

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:47:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-08-20T00:00:18', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '88fa8255-de86-4814-8d3e-635724880ef6'	System	20 Aug 2020 05:00:23
User entered '20 Aug 2020 00:00'	System	20 Aug 2020 05:00:23

US3012171

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:47:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
User entered '19 Aug 2020 12:00'	System	18 Aug 2020 21:19:51

US3012171

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:47:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
User entered '20 Aug 2020 11:59'	System	18 Aug 2020 21:19:51

US3012171

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
Data entry locked.	System	18 Aug 2020 21:19:51
User entered 'Day 3'	System	18 Aug 2020 21:19:51

US3012171

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:47:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-08-20T21:17:53', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: 'ba85b7ca-239d-49b9-8080-3521dafd8f7c'	System	21 Aug 2020 02:18:15
User entered 'Yes (Y)'	System	21 Aug 2020 02:18:15

US3012171

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:47:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-08-20T21:18:05', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: 'ba85b7ca-239d-49b9-8080-3521dafd8f7c'	System	21 Aug 2020 02:18:15
User entered '97.8'	System	21 Aug 2020 02:18:15

US3012171

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:47:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-08-20T21:18:09', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: 'ba85b7ca-239d-49b9-8080-3521dafd8f7c'	System	21 Aug 2020 02:18:15
User entered 'No (N)'	System	21 Aug 2020 02:18:15

US3012171

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:47:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-08-20T21:18:12', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: 'ba85b7ca-239d-49b9-8080-3521dafd8f7c'	System	21 Aug 2020 02:18:15
User entered '20 Aug 2020 21:18'	System	21 Aug 2020 02:18:15

US3012171

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:47:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
User entered '20 Aug 2020 12:00'	System	18 Aug 2020 21:19:51

US3012171

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:47:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
User entered '21 Aug 2020 11:59'	System	18 Aug 2020 21:19:51

US3012171

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
Data entry locked.	System	18 Aug 2020 21:19:51
User entered 'Day 4'	System	18 Aug 2020 21:19:51

US3012171

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:47:42

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-08-21T23:24:33', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '15fbff73-c02e-41c2-8a2c-4ed2d177fb28'	System	22 Aug 2020 04:24:49
User entered 'Yes (Y)'	System	22 Aug 2020 04:24:49

US3012171

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:47:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-08-21T23:24:40', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '15fbff73-c02e-41c2-8a2c-4ed2d177fb28'	System	22 Aug 2020 04:24:49
User entered '97.8'	System	22 Aug 2020 04:24:49

US3012171

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:47:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-08-21T23:24:43', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '15fbff73-c02e-41c2-8a2c-4ed2d177fb28'	System	22 Aug 2020 04:24:49
User entered 'No (N)'	System	22 Aug 2020 04:24:49

US3012171

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:47:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-08-21T23:24:45', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '15fbff73-c02e-41c2-8a2c-4ed2d177fb28'	System	22 Aug 2020 04:24:49
User entered '21 Aug 2020 23:24'	System	22 Aug 2020 04:24:49

US3012171

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:47:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
User entered '21 Aug 2020 12:00'	System	18 Aug 2020 21:19:51

US3012171

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:47:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
User entered '22 Aug 2020 11:59'	System	18 Aug 2020 21:19:51

US3012171

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
Data entry locked.	System	18 Aug 2020 21:19:51
User entered 'Day 5'	System	18 Aug 2020 21:19:51

US3012171

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:47:42

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-08-22T18:41:09', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: 'bb7b550b-2063-486e-8220-3a9ff159ad55'	System	22 Aug 2020 23:41:26
User entered 'Yes (Y)'	System	22 Aug 2020 23:41:26

US3012171

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:47:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-08-22T18:41:14', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: 'bb7b550b-2063-486e-8220-3a9ff159ad55'	System	22 Aug 2020 23:41:26
User entered '97.8'	System	22 Aug 2020 23:41:26

US3012171

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:47:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-08-22T18:41:17', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: 'bb7b550b-2063-486e-8220-3a9ff159ad55'	System	22 Aug 2020 23:41:26
User entered 'No (N)'	System	22 Aug 2020 23:41:26

US3012171

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:47:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-08-22T18:41:20', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: 'bb7b550b-2063-486e-8220-3a9ff159ad55'	System	22 Aug 2020 23:41:26
User entered '22 Aug 2020 18:41'	System	22 Aug 2020 23:41:26

US3012171

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:47:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
User entered '22 Aug 2020 12:00'	System	18 Aug 2020 21:19:51

US3012171

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:47:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
User entered '23 Aug 2020 11:59'	System	18 Aug 2020 21:19:51

US3012171

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
Data entry locked.	System	18 Aug 2020 21:19:51
User entered 'Day 6'	System	18 Aug 2020 21:19:51

US3012171

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:47:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-08-24T05:01:43', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '42e69baa-5424-47f9-8121-d55ff7e28b47'	System	24 Aug 2020 10:01:59
User entered 'Yes (Y)'	System	24 Aug 2020 10:01:59

US3012171

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:47:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-08-24T05:01:50', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '42e69baa-5424-47f9-8121-d55ff7e28b47'	System	24 Aug 2020 10:01:59
User entered '97.8'	System	24 Aug 2020 10:01:59

US3012171

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:47:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-08-24T05:01:53', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '42e69baa-5424-47f9-8121-d55ff7e28b47'	System	24 Aug 2020 10:01:59
User entered 'No (N)'	System	24 Aug 2020 10:01:59

US3012171

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:47:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-08-24T05:01:56', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '42e69baa-5424-47f9-8121-d55ff7e28b47'	System	24 Aug 2020 10:01:59
User entered '24 Aug 2020 05:01'	System	24 Aug 2020 10:01:59

US3012171

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:47:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
User entered '23 Aug 2020 12:00'	System	18 Aug 2020 21:19:51

US3012171

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:47:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
User entered '24 Aug 2020 11:59'	System	18 Aug 2020 21:19:51

US3012171

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
Data entry locked.	System	18 Aug 2020 21:19:51
User entered 'Day 7'	System	18 Aug 2020 21:19:51

US3012171

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:47:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-08-25T02:09:42', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '0eb9b77f-a589-4999-938c-a143a1057bde'	System	25 Aug 2020 07:10:03
User entered 'Yes (Y)'	System	25 Aug 2020 07:10:03

US3012171

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:47:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-08-25T02:09:53', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '0eb9b77f-a589-4999-938c-a143a1057bde'	System	25 Aug 2020 07:10:03
User entered '97.6'	System	25 Aug 2020 07:10:03

US3012171

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:47:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-08-25T02:09:56', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '0eb9b77f-a589-4999-938c-a143a1057bde'	System	25 Aug 2020 07:10:03
User entered 'No (N)'	System	25 Aug 2020 07:10:03

US3012171

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:47:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-08-25T02:09:59', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '0eb9b77f-a589-4999-938c-a143a1057bde'	System	25 Aug 2020 07:10:03
User entered '25 Aug 2020 02:09'	System	25 Aug 2020 07:10:03

US3012171

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:47:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
User entered '24 Aug 2020 12:00'	System	18 Aug 2020 21:19:51

US3012171

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:47:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
User entered '25 Aug 2020 11:59'	System	18 Aug 2020 21:19:51

US3012171

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
Data entry locked.	System	18 Aug 2020 21:19:51
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	18 Aug 2020 21:19:51

US3012171

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:47:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-08-18T16:38:50', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '998e0fd0-9921-4ea5-b0e4-8b9a34467844'	System	18 Aug 2020 21:39:40
User entered 'None (1)'	System	18 Aug 2020 21:39:40

US3012171

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:47:42

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-08-18T16:39:23', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '998e0fd0-9921-4ea5-b0e4-8b9a34467844'	System	18 Aug 2020 21:39:40
User entered 'No (N)'	System	18 Aug 2020 21:39:40

US3012171

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:47:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-08-18T16:39:26', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '998e0fd0-9921-4ea5-b0e4-8b9a34467844'	System	18 Aug 2020 21:39:40
User entered 'No (N)'	System	18 Aug 2020 21:39:40

US3012171

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:47:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-08-18T16:39:32', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '998e0fd0-9921-4ea5-b0e4-8b9a34467844'	System	18 Aug 2020 21:39:40
User entered 'None (1)'	System	18 Aug 2020 21:39:40

US3012171

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:47:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-08-18T16:39:36', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '998e0fd0-9921-4ea5-b0e4-8b9a34467844'	System	18 Aug 2020 21:39:40
User entered '18 Aug 2020 16:39'	System	18 Aug 2020 21:39:40

US3012171

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:47:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
User entered '18 Aug 2020 16:26'	System	18 Aug 2020 21:19:51

US3012171

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:47:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
User entered '18 Aug 2020 18:56'	System	18 Aug 2020 21:19:51

US3012171

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
Data entry locked.	System	18 Aug 2020 21:19:51
User entered 'Day 1, after vaccination (at home)'	System	18 Aug 2020 21:19:51

US3012171

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:47:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-08-18T21:06:28', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '93f52ab0-f036-486c-90f0-f413bcfa27be'	System	19 Aug 2020 02:06:48
User entered 'None (1)'	System	19 Aug 2020 02:06:48

US3012171

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:47:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-08-18T21:06:31', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '93f52ab0-f036-486c-90f0-f413bcfa27be'	System	19 Aug 2020 02:06:48
User entered 'No (N)'	System	19 Aug 2020 02:06:48

US3012171

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:47:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-08-18T21:06:34', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '93f52ab0-f036-486c-90f0-f413bcfa27be'	System	19 Aug 2020 02:06:48
User entered 'No (N)'	System	19 Aug 2020 02:06:48

US3012171

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:47:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-08-18T21:06:42', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '93f52ab0-f036-486c-90f0-f413bcfa27be'	System	19 Aug 2020 02:06:48
User entered 'None (1)'	System	19 Aug 2020 02:06:48

US3012171

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:47:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-08-18T21:06:45', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '93f52ab0-f036-486c-90f0-f413bcfa27be'	System	19 Aug 2020 02:06:48
User entered '18 Aug 2020 21:06'	System	19 Aug 2020 02:06:48

US3012171

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:47:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
User entered '18 Aug 2020 19:51'	System	18 Aug 2020 21:19:51

US3012171

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:47:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
User entered '19 Aug 2020 11:59'	System	18 Aug 2020 21:19:51

US3012171

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
Data entry locked.	System	18 Aug 2020 21:19:51
User entered 'Day 2'	System	18 Aug 2020 21:19:51

US3012171

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:47:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-08-20T00:00:27', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '44c65760-45ae-419d-a5f1-7b7d5d73a38e'	System	20 Aug 2020 05:00:43
User entered 'Does not interfere with activity (2)'	System	20 Aug 2020 05:00:43

US3012171

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:47:42

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-08-20T00:00:30', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '44c65760-45ae-419d-a5f1-7b7d5d73a38e'	System	20 Aug 2020 05:00:43
User entered 'No (N)'	System	20 Aug 2020 05:00:43

US3012171

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:47:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-08-20T00:00:33', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '44c65760-45ae-419d-a5f1-7b7d5d73a38e'	System	20 Aug 2020 05:00:43
User entered 'No (N)'	System	20 Aug 2020 05:00:43

US3012171

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:47:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-08-20T00:00:35', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '44c65760-45ae-419d-a5f1-7b7d5d73a38e'	System	20 Aug 2020 05:00:43
User entered 'None (1)'	System	20 Aug 2020 05:00:43

US3012171

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:47:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-08-20T00:00:38', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '44c65760-45ae-419d-a5f1-7b7d5d73a38e'	System	20 Aug 2020 05:00:43
User entered '20 Aug 2020 00:00'	System	20 Aug 2020 05:00:43

US3012171

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:47:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
User entered '19 Aug 2020 12:00'	System	18 Aug 2020 21:19:51

US3012171

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:47:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
User entered '20 Aug 2020 11:59'	System	18 Aug 2020 21:19:51

US3012171

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
Data entry locked.	System	18 Aug 2020 21:19:51
User entered 'Day 3'	System	18 Aug 2020 21:19:51

US3012171

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:47:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-08-20T21:18:18', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '4c4563cc-c73a-4f42-ad90-03a60dd2c60b'	System	21 Aug 2020 02:18:38
User entered 'Does not interfere with activity (2)'	System	21 Aug 2020 02:18:38

US3012171

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:47:42

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-08-20T21:18:22', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '4c4563cc-c73a-4f42-ad90-03a60dd2c60b'	System	21 Aug 2020 02:18:38
User entered 'No (N)'	System	21 Aug 2020 02:18:38

US3012171

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:47:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-08-20T21:18:28', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '4c4563cc-c73a-4f42-ad90-03a60dd2c60b'	System	21 Aug 2020 02:18:38
User entered 'No (N)'	System	21 Aug 2020 02:18:38

US3012171

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:47:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-08-20T21:18:32', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '4c4563cc-c73a-4f42-ad90-03a60dd2c60b'	System	21 Aug 2020 02:18:38
User entered 'None (1)'	System	21 Aug 2020 02:18:38

US3012171

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:47:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-08-20T21:18:34', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '4c4563cc-c73a-4f42-ad90-03a60dd2c60b'	System	21 Aug 2020 02:18:38
User entered '20 Aug 2020 21:18'	System	21 Aug 2020 02:18:38

US3012171

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:47:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
User entered '20 Aug 2020 12:00'	System	18 Aug 2020 21:19:51

US3012171

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:47:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
User entered '21 Aug 2020 11:59'	System	18 Aug 2020 21:19:51

US3012171

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
Data entry locked.	System	18 Aug 2020 21:19:51
User entered 'Day 4'	System	18 Aug 2020 21:19:51

US3012171

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:47:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-08-21T23:24:54', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: 'c725f332-b7cd-4230-9001-24c644fe9072'	System	22 Aug 2020 04:25:10
User entered 'Does not interfere with activity (2)'	System	22 Aug 2020 04:25:10

US3012171

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:47:42

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-08-21T23:24:57', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: 'c725f332-b7cd-4230-9001-24c644fe9072'	System	22 Aug 2020 04:25:10
User entered 'No (N)'	System	22 Aug 2020 04:25:10

US3012171

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:47:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-08-21T23:24:59', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: 'c725f332-b7cd-4230-9001-24c644fe9072'	System	22 Aug 2020 04:25:10
User entered 'No (N)'	System	22 Aug 2020 04:25:10

US3012171

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:47:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-08-21T23:25:02', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: 'c725f332-b7cd-4230-9001-24c644fe9072'	System	22 Aug 2020 04:25:10
User entered 'None (1)'	System	22 Aug 2020 04:25:10

US3012171

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:47:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-08-21T23:25:05', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: 'c725f332-b7cd-4230-9001-24c644fe9072'	System	22 Aug 2020 04:25:10
User entered '21 Aug 2020 23:25'	System	22 Aug 2020 04:25:10

US3012171

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:47:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
User entered '21 Aug 2020 12:00'	System	18 Aug 2020 21:19:51

US3012171

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:47:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
User entered '22 Aug 2020 11:59'	System	18 Aug 2020 21:19:51

US3012171

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
Data entry locked.	System	18 Aug 2020 21:19:51
User entered 'Day 5'	System	18 Aug 2020 21:19:51

US3012171

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:47:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-08-22T18:41:24', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: 'e741849c-6dac-41ea-baa1-f9e805c8921e'	System	22 Aug 2020 23:41:38
User entered 'None (1)'	System	22 Aug 2020 23:41:38

US3012171

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:47:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-08-22T18:41:27', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: 'e741849c-6dac-41ea-baa1-f9e805c8921e'	System	22 Aug 2020 23:41:38
User entered 'No (N)'	System	22 Aug 2020 23:41:38

US3012171

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:47:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-08-22T18:41:29', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: 'e741849c-6dac-41ea-baa1-f9e805c8921e'	System	22 Aug 2020 23:41:38
User entered 'No (N)'	System	22 Aug 2020 23:41:38

US3012171

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:47:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-08-22T18:41:32', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: 'e741849c-6dac-41ea-baa1-f9e805c8921e'	System	22 Aug 2020 23:41:38
User entered 'None (1)'	System	22 Aug 2020 23:41:38

US3012171

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:47:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-08-22T18:41:34', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: 'e741849c-6dac-41ea-baa1-f9e805c8921e'	System	22 Aug 2020 23:41:38
User entered '22 Aug 2020 18:41'	System	22 Aug 2020 23:41:38

US3012171

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:47:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
User entered '22 Aug 2020 12:00'	System	18 Aug 2020 21:19:51

US3012171

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:47:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
User entered '23 Aug 2020 11:59'	System	18 Aug 2020 21:19:51

US3012171

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
Data entry locked.	System	18 Aug 2020 21:19:51
User entered 'Day 6'	System	18 Aug 2020 21:19:51

US3012171

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:47:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-08-24T05:02:01', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '32cc9217-b3c3-4e33-a7d9-0f14dd76c8a7'	System	24 Aug 2020 10:02:17
User entered 'None (1)'	System	24 Aug 2020 10:02:17

US3012171

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:47:42

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-08-24T05:02:04', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '32cc9217-b3c3-4e33-a7d9-0f14dd76c8a7'	System	24 Aug 2020 10:02:17
User entered 'No (N)'	System	24 Aug 2020 10:02:17

US3012171

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:47:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-08-24T05:02:07', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '32cc9217-b3c3-4e33-a7d9-0f14dd76c8a7'	System	24 Aug 2020 10:02:17
User entered 'No (N)'	System	24 Aug 2020 10:02:17

US3012171

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:47:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-08-24T05:02:10', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '32cc9217-b3c3-4e33-a7d9-0f14dd76c8a7'	System	24 Aug 2020 10:02:17
User entered 'None (1)'	System	24 Aug 2020 10:02:17

US3012171

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:47:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-08-24T05:02:12', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '32cc9217-b3c3-4e33-a7d9-0f14dd76c8a7'	System	24 Aug 2020 10:02:17
User entered '24 Aug 2020 05:02'	System	24 Aug 2020 10:02:17

US3012171

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:47:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
User entered '23 Aug 2020 12:00'	System	18 Aug 2020 21:19:51

US3012171

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:47:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
User entered '24 Aug 2020 11:59'	System	18 Aug 2020 21:19:51

US3012171

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
Data entry locked.	System	18 Aug 2020 21:19:51
User entered 'Day 7'	System	18 Aug 2020 21:19:51

US3012171

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:47:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-08-25T02:10:03', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '7880ac29-13dc-4065-abe7-d9e759740876'	System	25 Aug 2020 07:10:19
User entered 'None (1)'	System	25 Aug 2020 07:10:19

US3012171

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:47:42

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-08-25T02:10:06', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '7880ac29-13dc-4065-abe7-d9e759740876'	System	25 Aug 2020 07:10:19
User entered 'No (N)'	System	25 Aug 2020 07:10:19

US3012171

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:47:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-08-25T02:10:09', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '7880ac29-13dc-4065-abe7-d9e759740876'	System	25 Aug 2020 07:10:19
User entered 'No (N)'	System	25 Aug 2020 07:10:19

US3012171

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:47:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-08-25T02:10:12', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '7880ac29-13dc-4065-abe7-d9e759740876'	System	25 Aug 2020 07:10:19
User entered 'None (1)'	System	25 Aug 2020 07:10:19

US3012171

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:47:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-08-25T02:10:15', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '7880ac29-13dc-4065-abe7-d9e759740876'	System	25 Aug 2020 07:10:19
User entered '25 Aug 2020 02:10'	System	25 Aug 2020 07:10:19

US3012171

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:47:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
User entered '24 Aug 2020 12:00'	System	18 Aug 2020 21:19:51

US3012171

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:47:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
User entered '25 Aug 2020 11:59'	System	18 Aug 2020 21:19:51

US3012171

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
Data entry locked.	System	18 Aug 2020 21:19:51
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	18 Aug 2020 21:19:51

US3012171

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:47:42

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-08-18T16:39:41', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '4f8e1304-aec4-4aa7-b068-723999b9afa6'	System	18 Aug 2020 21:40:09
User entered 'None (0)'	System	18 Aug 2020 21:40:09

US3012171

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:47:42

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-08-18T16:39:46', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '4f8e1304-aec4-4aa7-b068-723999b9afa6'	System	18 Aug 2020 21:40:09
User entered 'None (0)'	System	18 Aug 2020 21:40:09

US3012171

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:47:42

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-08-18T16:39:48', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '4f8e1304-aec4-4aa7-b068-723999b9afa6'	System	18 Aug 2020 21:40:09
User entered 'None (0)'	System	18 Aug 2020 21:40:09

US3012171

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:47:42

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-08-18T16:39:50', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '4f8e1304-aec4-4aa7-b068-723999b9afa6'	System	18 Aug 2020 21:40:09
User entered 'None (0)'	System	18 Aug 2020 21:40:09

US3012171

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:47:42

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-08-18T16:39:52', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '4f8e1304-aec4-4aa7-b068-723999b9afa6'	System	18 Aug 2020 21:40:09
User entered 'None (0)'	System	18 Aug 2020 21:40:09

US3012171

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:47:42

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-08-18T16:39:55', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '4f8e1304-aec4-4aa7-b068-723999b9afa6'	System	18 Aug 2020 21:40:09
User entered 'None (0)'	System	18 Aug 2020 21:40:09

US3012171

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:47:42

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)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-08-18T16:40:03', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '4f8e1304-aec4-4aa7-b068-723999b9afa6'	System	18 Aug 2020 21:40:09
User entered 'No (N)'	System	18 Aug 2020 21:40:09

US3012171

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:47:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-08-18T16:40:06', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '4f8e1304-aec4-4aa7-b068-723999b9afa6'	System	18 Aug 2020 21:40:09
User entered '18 Aug 2020 16:40'	System	18 Aug 2020 21:40:09

US3012171

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:47:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
User entered '18 Aug 2020 16:26'	System	18 Aug 2020 21:19:51

US3012171

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:47:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
User entered '18 Aug 2020 18:56'	System	18 Aug 2020 21:19:51

US3012171

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
Data entry locked.	System	18 Aug 2020 21:19:51
User entered 'Day 1, after vaccination (at home)'	System	18 Aug 2020 21:19:51

US3012171

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:47:42

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-08-18T21:06:51', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '049e502e-3816-43bd-8ff8-1b68ff7cd680'	System	19 Aug 2020 02:07:19
User entered 'None (0)'	System	19 Aug 2020 02:07:19

US3012171

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:47:42

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-08-18T21:06:57', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '049e502e-3816-43bd-8ff8-1b68ff7cd680'	System	19 Aug 2020 02:07:19
User entered 'None (0)'	System	19 Aug 2020 02:07:19

US3012171

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:47:42

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-08-18T21:06:59', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '049e502e-3816-43bd-8ff8-1b68ff7cd680'	System	19 Aug 2020 02:07:19
User entered 'None (0)'	System	19 Aug 2020 02:07:19

US3012171

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:47:42

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-08-18T21:07:02', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '049e502e-3816-43bd-8ff8-1b68ff7cd680'	System	19 Aug 2020 02:07:19
User entered 'None (0)'	System	19 Aug 2020 02:07:19

US3012171

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:47:42

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-08-18T21:07:04', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '049e502e-3816-43bd-8ff8-1b68ff7cd680'	System	19 Aug 2020 02:07:19
User entered 'None (0)'	System	19 Aug 2020 02:07:19

US3012171

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:47:42

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-08-18T21:07:07', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '049e502e-3816-43bd-8ff8-1b68ff7cd680'	System	19 Aug 2020 02:07:19
User entered 'None (0)'	System	19 Aug 2020 02:07:19

US3012171

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:47:42

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)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-08-18T21:07:13', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '049e502e-3816-43bd-8ff8-1b68ff7cd680'	System	19 Aug 2020 02:07:19
User entered 'No (N)'	System	19 Aug 2020 02:07:19

US3012171

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:47:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-08-18T21:07:16', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '049e502e-3816-43bd-8ff8-1b68ff7cd680'	System	19 Aug 2020 02:07:19
User entered '18 Aug 2020 21:07'	System	19 Aug 2020 02:07:19

US3012171

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:47:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
User entered '18 Aug 2020 19:51'	System	18 Aug 2020 21:19:51

US3012171

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:47:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
User entered '19 Aug 2020 11:59'	System	18 Aug 2020 21:19:51

US3012171

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
Data entry locked.	System	18 Aug 2020 21:19:51
User entered 'Day 2'	System	18 Aug 2020 21:19:51

US3012171

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:47:42

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-08-20T00:00:42', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '61665cd9-d88f-419b-911c-24943808523b'	System	20 Aug 2020 05:01:05
User entered 'None (0)'	System	20 Aug 2020 05:01:05

US3012171

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:47:42

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-08-20T00:00:46', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '61665cd9-d88f-419b-911c-24943808523b'	System	20 Aug 2020 05:01:05
User entered 'None (0)'	System	20 Aug 2020 05:01:05

US3012171

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:47:42

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-08-20T00:00:48', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '61665cd9-d88f-419b-911c-24943808523b'	System	20 Aug 2020 05:01:05
User entered 'None (0)'	System	20 Aug 2020 05:01:05

US3012171

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:47:42

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-08-20T00:00:51', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '61665cd9-d88f-419b-911c-24943808523b'	System	20 Aug 2020 05:01:05
User entered 'None (0)'	System	20 Aug 2020 05:01:05

US3012171

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:47:42

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-08-20T00:00:53', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '61665cd9-d88f-419b-911c-24943808523b'	System	20 Aug 2020 05:01:05
User entered 'None (0)'	System	20 Aug 2020 05:01:05

US3012171

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:47:42

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-08-20T00:00:56', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '61665cd9-d88f-419b-911c-24943808523b'	System	20 Aug 2020 05:01:05
User entered 'None (0)'	System	20 Aug 2020 05:01:05

US3012171

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:47:42

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)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-08-20T00:01:00', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '61665cd9-d88f-419b-911c-24943808523b'	System	20 Aug 2020 05:01:05
User entered 'No (N)'	System	20 Aug 2020 05:01:05

US3012171

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:47:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-08-20T00:01:02', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '61665cd9-d88f-419b-911c-24943808523b'	System	20 Aug 2020 05:01:05
User entered '20 Aug 2020 00:01'	System	20 Aug 2020 05:01:05

US3012171

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:47:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
User entered '19 Aug 2020 12:00'	System	18 Aug 2020 21:19:51

US3012171

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:47:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
User entered '20 Aug 2020 11:59'	System	18 Aug 2020 21:19:51

US3012171

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
Data entry locked.	System	18 Aug 2020 21:19:51
User entered 'Day 3'	System	18 Aug 2020 21:19:51

US3012171

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:47:42

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-08-20T21:18:39', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '340a156e-ce8f-4dc1-a58e-83626a275d67'	System	21 Aug 2020 02:19:08
User entered 'None (0)'	System	21 Aug 2020 02:19:08

US3012171

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:47:42

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-08-20T21:18:46', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '340a156e-ce8f-4dc1-a58e-83626a275d67'	System	21 Aug 2020 02:19:08
User entered 'None (0)'	System	21 Aug 2020 02:19:08

US3012171

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:47:42

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-08-20T21:18:49', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '340a156e-ce8f-4dc1-a58e-83626a275d67'	System	21 Aug 2020 02:19:08
User entered 'No interference with activity (1)'	System	21 Aug 2020 02:19:08

US3012171

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:47:42

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-08-20T21:18:53', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '340a156e-ce8f-4dc1-a58e-83626a275d67'	System	21 Aug 2020 02:19:08
User entered 'No interference with activity (1)'	System	21 Aug 2020 02:19:08

US3012171

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:47:42

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-08-20T21:18:55', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '340a156e-ce8f-4dc1-a58e-83626a275d67'	System	21 Aug 2020 02:19:08
User entered 'None (0)'	System	21 Aug 2020 02:19:08

US3012171

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:47:42

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-08-20T21:18:58', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '340a156e-ce8f-4dc1-a58e-83626a275d67'	System	21 Aug 2020 02:19:08
User entered 'None (0)'	System	21 Aug 2020 02:19:08

US3012171

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:47:42

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)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-08-20T21:19:02', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '340a156e-ce8f-4dc1-a58e-83626a275d67'	System	21 Aug 2020 02:19:08
User entered 'No (N)'	System	21 Aug 2020 02:19:08

US3012171

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:47:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-08-20T21:19:04', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '340a156e-ce8f-4dc1-a58e-83626a275d67'	System	21 Aug 2020 02:19:08
User entered '20 Aug 2020 21:19'	System	21 Aug 2020 02:19:08

US3012171

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:47:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
User entered '20 Aug 2020 12:00'	System	18 Aug 2020 21:19:51

US3012171

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:47:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
User entered '21 Aug 2020 11:59'	System	18 Aug 2020 21:19:51

US3012171

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
Data entry locked.	System	18 Aug 2020 21:19:51
User entered 'Day 4'	System	18 Aug 2020 21:19:51

US3012171

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:47:42

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-08-21T23:25:09', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '239b719d-36a2-4ce2-8341-695b30b6bc23'	System	22 Aug 2020 04:25:31
User entered 'None (0)'	System	22 Aug 2020 04:25:31

US3012171

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:47:42

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-08-21T23:25:11', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '239b719d-36a2-4ce2-8341-695b30b6bc23'	System	22 Aug 2020 04:25:31
User entered 'None (0)'	System	22 Aug 2020 04:25:31

US3012171

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:47:42

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-08-21T23:25:16', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '239b719d-36a2-4ce2-8341-695b30b6bc23'	System	22 Aug 2020 04:25:31
User entered 'No interference with activity (1)'	System	22 Aug 2020 04:25:31

US3012171

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:47:42

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-08-21T23:25:18', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '239b719d-36a2-4ce2-8341-695b30b6bc23'	System	22 Aug 2020 04:25:31
User entered 'No interference with activity (1)'	System	22 Aug 2020 04:25:31

US3012171

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:47:42

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-08-21T23:25:20', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '239b719d-36a2-4ce2-8341-695b30b6bc23'	System	22 Aug 2020 04:25:31
User entered 'None (0)'	System	22 Aug 2020 04:25:31

US3012171

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:47:42

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-08-21T23:25:22', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '239b719d-36a2-4ce2-8341-695b30b6bc23'	System	22 Aug 2020 04:25:31
User entered 'None (0)'	System	22 Aug 2020 04:25:31

US3012171

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:47:42

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)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-08-21T23:25:25', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '239b719d-36a2-4ce2-8341-695b30b6bc23'	System	22 Aug 2020 04:25:31
User entered 'No (N)'	System	22 Aug 2020 04:25:31

US3012171

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:47:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-08-21T23:25:27', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '239b719d-36a2-4ce2-8341-695b30b6bc23'	System	22 Aug 2020 04:25:31
User entered '21 Aug 2020 23:25'	System	22 Aug 2020 04:25:31

US3012171

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:47:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
User entered '21 Aug 2020 12:00'	System	18 Aug 2020 21:19:51

US3012171

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:47:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
User entered '22 Aug 2020 11:59'	System	18 Aug 2020 21:19:51

US3012171

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
Data entry locked.	System	18 Aug 2020 21:19:51
User entered 'Day 5'	System	18 Aug 2020 21:19:51

US3012171

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:47:42

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-08-22T18:41:38', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '90a33b98-e579-4bd2-89c0-f7f8d8fa3fcf'	System	22 Aug 2020 23:41:56
User entered 'None (0)'	System	22 Aug 2020 23:41:56

US3012171

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:47:42

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-08-22T18:41:40', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '90a33b98-e579-4bd2-89c0-f7f8d8fa3fcf'	System	22 Aug 2020 23:41:56
User entered 'None (0)'	System	22 Aug 2020 23:41:56

US3012171

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:47:42

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-08-22T18:41:42', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '90a33b98-e579-4bd2-89c0-f7f8d8fa3fcf'	System	22 Aug 2020 23:41:56
User entered 'None (0)'	System	22 Aug 2020 23:41:56

US3012171

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:47:42

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-08-22T18:41:44', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '90a33b98-e579-4bd2-89c0-f7f8d8fa3fcf'	System	22 Aug 2020 23:41:56
User entered 'None (0)'	System	22 Aug 2020 23:41:56

US3012171

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:47:42

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-08-22T18:41:46', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '90a33b98-e579-4bd2-89c0-f7f8d8fa3fcf'	System	22 Aug 2020 23:41:56
User entered 'None (0)'	System	22 Aug 2020 23:41:56

US3012171

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:47:42

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-08-22T18:41:47', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '90a33b98-e579-4bd2-89c0-f7f8d8fa3fcf'	System	22 Aug 2020 23:41:56
User entered 'None (0)'	System	22 Aug 2020 23:41:56

US3012171

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:47:42

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)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-08-22T18:41:51', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '90a33b98-e579-4bd2-89c0-f7f8d8fa3fcf'	System	22 Aug 2020 23:41:56
User entered 'No (N)'	System	22 Aug 2020 23:41:56

US3012171

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:47:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-08-22T18:41:53', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '90a33b98-e579-4bd2-89c0-f7f8d8fa3fcf'	System	22 Aug 2020 23:41:56
User entered '22 Aug 2020 18:41'	System	22 Aug 2020 23:41:56

US3012171

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:47:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
User entered '22 Aug 2020 12:00'	System	18 Aug 2020 21:19:51

US3012171

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:47:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
User entered '23 Aug 2020 11:59'	System	18 Aug 2020 21:19:51

US3012171

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
Data entry locked.	System	18 Aug 2020 21:19:51
User entered 'Day 6'	System	18 Aug 2020 21:19:51

US3012171

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:47:42

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-08-24T05:02:20', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: 'b9339643-1b83-48cd-84fa-ac58e7a7938d'	System	24 Aug 2020 10:02:46
User entered 'None (0)'	System	24 Aug 2020 10:02:46

US3012171

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:47:42

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-08-24T05:02:24', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: 'b9339643-1b83-48cd-84fa-ac58e7a7938d'	System	24 Aug 2020 10:02:46
User entered 'None (0)'	System	24 Aug 2020 10:02:46

US3012171

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:47:42

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-08-24T05:02:29', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: 'b9339643-1b83-48cd-84fa-ac58e7a7938d'	System	24 Aug 2020 10:02:46
User entered 'None (0)'	System	24 Aug 2020 10:02:46

US3012171

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:47:42

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-08-24T05:02:31', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: 'b9339643-1b83-48cd-84fa-ac58e7a7938d'	System	24 Aug 2020 10:02:46
User entered 'No interference with activity (1)'	System	24 Aug 2020 10:02:46

US3012171

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:47:42

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-08-24T05:02:35', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: 'b9339643-1b83-48cd-84fa-ac58e7a7938d'	System	24 Aug 2020 10:02:46
User entered 'None (0)'	System	24 Aug 2020 10:02:46

US3012171

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:47:42

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-08-24T05:02:37', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: 'b9339643-1b83-48cd-84fa-ac58e7a7938d'	System	24 Aug 2020 10:02:46
User entered 'None (0)'	System	24 Aug 2020 10:02:46

US3012171

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:47:42

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)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-08-24T05:02:40', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: 'b9339643-1b83-48cd-84fa-ac58e7a7938d'	System	24 Aug 2020 10:02:46
User entered 'No (N)'	System	24 Aug 2020 10:02:46

US3012171

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:47:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-08-24T05:02:42', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: 'b9339643-1b83-48cd-84fa-ac58e7a7938d'	System	24 Aug 2020 10:02:46
User entered '24 Aug 2020 05:02'	System	24 Aug 2020 10:02:46

US3012171

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:47:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
User entered '23 Aug 2020 12:00'	System	18 Aug 2020 21:19:51

US3012171

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:47:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
User entered '24 Aug 2020 11:59'	System	18 Aug 2020 21:19:51

US3012171

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
Data entry locked.	System	18 Aug 2020 21:19:51
User entered 'Day 7'	System	18 Aug 2020 21:19:51

US3012171

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:47:42

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-08-25T02:10:19', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: 'b22ebbae-bd5d-4b8e-acba-22b5ce4d99cf'	System	25 Aug 2020 07:10:41
User entered 'None (0)'	System	25 Aug 2020 07:10:41

US3012171

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:47:42

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-08-25T02:10:25', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: 'b22ebbae-bd5d-4b8e-acba-22b5ce4d99cf'	System	25 Aug 2020 07:10:41
User entered 'None (0)'	System	25 Aug 2020 07:10:41

US3012171

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:47:42

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-08-25T02:10:28', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: 'b22ebbae-bd5d-4b8e-acba-22b5ce4d99cf'	System	25 Aug 2020 07:10:41
User entered 'None (0)'	System	25 Aug 2020 07:10:41

US3012171

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:47:42

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-08-25T02:10:31', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: 'b22ebbae-bd5d-4b8e-acba-22b5ce4d99cf'	System	25 Aug 2020 07:10:41
User entered 'None (0)'	System	25 Aug 2020 07:10:41

US3012171

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:47:42

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-08-25T02:10:32', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: 'b22ebbae-bd5d-4b8e-acba-22b5ce4d99cf'	System	25 Aug 2020 07:10:41
User entered 'None (0)'	System	25 Aug 2020 07:10:41

US3012171

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:47:42

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-08-25T02:10:34', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: 'b22ebbae-bd5d-4b8e-acba-22b5ce4d99cf'	System	25 Aug 2020 07:10:41
User entered 'None (0)'	System	25 Aug 2020 07:10:41

US3012171

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:47:42

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)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-08-25T02:10:37', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: 'b22ebbae-bd5d-4b8e-acba-22b5ce4d99cf'	System	25 Aug 2020 07:10:41
User entered 'No (N)'	System	25 Aug 2020 07:10:41

US3012171

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:47:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-08-25T02:10:39', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: 'b22ebbae-bd5d-4b8e-acba-22b5ce4d99cf'	System	25 Aug 2020 07:10:41
User entered '25 Aug 2020 02:10'	System	25 Aug 2020 07:10:41

US3012171

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:47:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
User entered '24 Aug 2020 12:00'	System	18 Aug 2020 21:19:51

US3012171

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:47:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
User entered '25 Aug 2020 11:59'	System	18 Aug 2020 21:19:51

US3012171

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:47:42

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered 'Yes (Y)'	(b) (4) Tambra Dora (b) (4)	31 Aug 2020 16:46:02

US3012171

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:47:42

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User closed query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	01 Sep 2020 11:30:41
Query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'Date is correct as entered. ' (Site from System).	Tambra Dora (b) (4) (b) (4)	31 Aug 2020 16:46:17
User opened query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	31 Aug 2020 16:46:02
User entered '31 Aug 2020'	Tambra Dora (b) (4) (b) (4)	31 Aug 2020 16:46:02

US3012171

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:47:42

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered 'Contact Made (CONTACT MADE)'	Tambra Dora (b) (4)	31 Aug 2020 16:46:02

US3012171

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:47:42

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered empty.	Tambra Dora (b) (4)	31 Aug 2020 16:46:02

US3012171

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:47:42

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered 'Yes (Y)'	(b) (4) Tambra Dora (b) (4)	31 Aug 2020 16:46:23

US3012171

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:47:42

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User entered 'I'	System	31 Aug 2020 16:46:23

US3012171

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:47:42

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered 'Yes (Y)'	(b) (4) Tambra Dora (b) (4)	02 Sep 2020 23:03:30

US3012171

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:47:42

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered '2 Sep 2020'	Tambra Dora (b) (4)	02 Sep 2020 23:03:30

US3012171

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:47:42

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered 'Contact Made (CONTACT MADE)'	Tambra Dora (b) (4)	02 Sep 2020 23:03:30

US3012171

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:47:42

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered empty.	(b) (4) Tambra Dora (b) (4) (b) (4)	02 Sep 2020 23:03:30

US3012171

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:47:42

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered 'Yes (Y)'	(b) (4) Tambra Dora (b) (4) (b) (4)	02 Sep 2020 23:03:33

US3012171

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:47:42

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User entered 'I'	System	02 Sep 2020 23:03:33

US3012171

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:47:42

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered 'Yes (Y)'	(b) (4) Tambra Dora (b) (4)	08 Sep 2020 20:43:58

US3012171

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:47:42

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered '8 Sep 2020'	Tambra Dora (b) (4)	08 Sep 2020 20:43:58

US3012171

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:47:42

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered 'Contact Made (CONTACT MADE)'	Tambra Dora (b) (4)	08 Sep 2020 20:43:58

US3012171

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:47:42

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered empty.	(b) (4) Tambra Dora (b) (4) (b) (4)	08 Sep 2020 20:43:58

US3012171

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:47:42

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered 'Yes (Y)'	(b) (4) Tambra Dora (b) (4)	08 Sep 2020 20:44:01

US3012171

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:47:42

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User entered 'I'	System	08 Sep 2020 20:44:01

US3012171

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:47:42

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered 'Yes (Y)'	Jennifer Leyva (b) (4)	15 Sep 2020 15:50:24

US3012171

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:47:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered '15 Sep 2020'	Jennifer Leyva (b) (4)	15 Sep 2020 15:50:24

US3012171

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:47:42

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered 'Clinic (Clinic)'	Jennifer Leyva (b) (4)	15 Sep 2020 15:50:24

US3012171

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:47:42

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User entered 'VISIT2'	System	15 Sep 2020 15:50:24

US3012171

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:47:42

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User accepted default value 'Pre-Dose (PREDOSE)'	Jennifer Leyva (b) (4) (b) (4)	15 Sep 2020 15:50:53

US3012171

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:47:42

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered 'Yes (Y)'	Jennifer Leyva (b) (4)	15 Sep 2020 15:50:53

US3012171

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:47:42

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered '15 Sep 2020'	Jennifer Leyva (b) (4)	15 Sep 2020 15:50:53

US3012171

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:47:42

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered '10:10'	Jennifer Leyva (b) (4)	15 Sep 2020 15:50:53

US3012171

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:47:42

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User entered '15 Sep 2020 10:10'	System	15 Sep 2020 15:50:53

US3012171

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:47:42

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered '99.2' F	Jennifer Leyva (b) (4)	15 Sep 2020 15:50:53

US3012171

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:47:42

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered 'Oral (Oral)'	Jennifer Leyva (b) (4)	15 Sep 2020 15:50:53

US3012171

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:47:42

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered empty.	Jennifer Leyva (b) (4)	15 Sep 2020 15:50:53

US3012171

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:47:42

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered '101'	Jennifer Leyva (b) (4)	15 Sep 2020 15:50:53

US3012171

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:47:42

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User entered 'bpm'	System	15 Sep 2020 15:50:53

US3012171

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:47:42

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered '18'	Jennifer Leyva (b) (4)	15 Sep 2020 15:50:53

US3012171

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:47:42

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User entered 'breaths/min'	System	15 Sep 2020 15:50:53

US3012171

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:47:42

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered '115'	Jennifer Leyva (b) (4)	15 Sep 2020 15:50:53

US3012171

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:47:42

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User entered 'mmHg'	System	15 Sep 2020 15:50:53

US3012171

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:47:42

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered '75'	Jennifer Leyva (b) (4)	15 Sep 2020 15:50:53

US3012171

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:47:42

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User entered 'mmHg'	System	15 Sep 2020 15:50:53

US3012171

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:47:42

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User accepted default value 'Post-Dose (POSTDOSE)'	Jennifer Leyva (b) (4) (b) (4)	16 Sep 2020 22:15:53

US3012171

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:47:42

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered 'Yes (Y)'	Jennifer Leyva (b) (4)	16 Sep 2020 22:15:53

US3012171

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:47:42

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered '15 Sep 2020'	Jennifer Leyva (b) (4)	16 Sep 2020 22:15:53

US3012171

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:47:42

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered '11:46'	Jennifer Leyva (b) (4)	16 Sep 2020 22:15:53

US3012171

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:47:42

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User entered '15 Sep 2020 11:46'	System	16 Sep 2020 22:15:53

US3012171

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:47:42

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered '98.1' F	Jennifer Leyva (b) (4)	16 Sep 2020 22:15:53

US3012171

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:47:42

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered 'Oral (Oral)'	Jennifer Leyva (b) (4)	16 Sep 2020 22:15:53

US3012171

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:47:42

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered empty.	Jennifer Leyva (b) (4)	16 Sep 2020 22:15:53

US3012171

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:47:42

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered '96'	Jennifer Leyva (b) (4)	16 Sep 2020 22:15:53

US3012171

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:47:42

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User entered 'bpm'	System	16 Sep 2020 22:15:53

US3012171

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:47:42

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered '14'	Jennifer Leyva (b) (4)	16 Sep 2020 22:15:53

US3012171

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:47:42

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User entered 'breaths/min'	System	16 Sep 2020 22:15:53

US3012171

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:47:42

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered '108'	Jennifer Leyva (b) (4)	16 Sep 2020 22:15:53

US3012171

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:47:42

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User entered 'mmHg'	System	16 Sep 2020 22:15:53

US3012171

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:47:42

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered '77'	Jennifer Leyva (b) (4)	16 Sep 2020 22:15:53

US3012171

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:47:42

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User entered 'mmHg'	System	16 Sep 2020 22:15:53

US3012171

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:47:42

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered 'Yes (Y)'	Jennifer Leyva (b) (4)	15 Sep 2020 15:51:04

US3012171

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:47:42

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered '15 Sep 2020'	Jennifer Leyva (b) (4)	15 Sep 2020 15:51:04

US3012171

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:47:42

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered 'Yes (Y)'	Jennifer Leyva (b) (4)	15 Sep 2020 16:35:07

US3012171

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:47:42

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered empty.	Jennifer Leyva (b) (4)	15 Sep 2020 16:35:07

US3012171

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:47:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered empty.	Jennifer Leyva (b) (4)	15 Sep 2020 16:35:07

US3012171

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:47:42

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User entered 'MRNA-1273 OR PLACEBO'	System	15 Sep 2020 16:35:07

US3012171

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:47:42

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered '15 Sep 2020'	Jennifer Leyva (b) (4)	15 Sep 2020 16:35:07

US3012171

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:47:42

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered '11:01'	Jennifer Leyva (b) (4)	15 Sep 2020 16:35:07

US3012171

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:47:42

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User entered '15 Sep 2020 11:01'	System	15 Sep 2020 16:35:07

US3012171

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:47:42

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered 'Left Arm (LEFT ARM)'	Jennifer Leyva (b) (4)	15 Sep 2020 16:35:07

US3012171

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:47:42

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User entered 'ONCE'	System	15 Sep 2020 16:35:07

US3012171

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:47:42

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User entered 'INTRAMUSCULAR'	System	15 Sep 2020 16:35:07

US3012171

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:47:42

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered 'Yes (Y)'	Jennifer Leyva (b) (4)	15 Sep 2020 15:51:17

US3012171

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:47:42

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 15SEP2020 is recorded under Visit 2 Day 29 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). Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 15SEP2020 is recorded under Visit 2 Day 29 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 Day 29, visit on 15SEP2020' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Nov 2020 18:16:39
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 15SEP2020 is recorded under Visit 2 Day 29 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) (b) (4)	20 Oct 2020 13:59:55
User entered '15 Sep 2020'	(b) (4), (b) (6)	19 Oct 2020 04:44:19
	Jennifer Leyva (b) (4) (b) (4)	15 Sep 2020 15:51:17

US3012171

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:47:42

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered '10:37'	Jennifer Leyva (b) (4)	15 Sep 2020 15:51:17

US3012171

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:47:42

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User entered '15 Sep 2020 10:37'	System	15 Sep 2020 15:51:17

US3012171

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 14:47:42

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User closed query 'Per GCL Lab Recon: it appears GCL has this as an Unscheduled Visit. Please review and confirm 15SEP2020 is for Day 29 or clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Nov 2020 18:56:13
Query 'Per GCL Lab Recon: it appears GCL has this as an Unscheduled Visit. Please review and confirm 15SEP2020 is for Day 29 or clarify.' answered with 'Unscheduled lab kit was used but sample is for Day 29 visit, 15SEP2020' (Site from DM).	Jennifer Leyva (b) (4) (b) (4)	20 Oct 2020 13:30:36
User opened query 'Per GCL Lab Recon: it appears GCL has this as an Unscheduled Visit. Please review and confirm 15SEP2020 is for Day 29 or clarify.' (Site from DM).	(b) (4), (b) (6)	18 Oct 2020 15:27:21
User entered '15 Sep 2020'	Jennifer Leyva (b) (4) (b) (4)	15 Sep 2020 15:51:28

US3012171

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:47:42

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Jennifer Leyva (b) (4) (b) (4)	15 Sep 2020 15:51:28

US3012171

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:47:42

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered 'Yes (Y)'	Jennifer Leyva (b) (4)	15 Sep 2020 15:51:28

US3012171

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:47:42

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered '10:24'	Jennifer Leyva (b) (4)	15 Sep 2020 15:51:28

US3012171

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:47:42

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User entered '15 Sep 2020 10:24'	System	15 Sep 2020 15:51:28

US3012171

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:47:42

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Jennifer Leyva (b) (4) (b) (4)	15 Sep 2020 15:51:28

US3012171

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:47:42

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered 'No (N)'	Jennifer Leyva (b) (4)	15 Sep 2020 15:51:28

US3012171

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:47:42

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered empty.	Jennifer Leyva (b) (4)	15 Sep 2020 15:51:28

US3012171

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:47:42

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User entered empty.	System	15 Sep 2020 15:51:28

US3012171

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:47:42

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered 'Yes (Y)'	Jennifer Leyva (b) (4)	15 Sep 2020 15:51:32

US3012171

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:47:42

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User entered 'I'	System	15 Sep 2020 15:51:32

US3012171

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
Data entry locked.	System	15 Sep 2020 16:35:07
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	15 Sep 2020 16:35:07

US3012171

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:47:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-09-15T11:36:40', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '80a88349-15f3-4df6-81a9-76b399417e09'	System	15 Sep 2020 16:37:06
User entered 'Yes (Y)'	System	15 Sep 2020 16:37:06

US3012171

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:47:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-09-15T11:36:55', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '80a88349-15f3-4df6-81a9-76b399417e09'	System	15 Sep 2020 16:37:06
User entered '98.1'	System	15 Sep 2020 16:37:06

US3012171

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:47:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-09-15T11:36:58', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '80a88349-15f3-4df6-81a9-76b399417e09'	System	15 Sep 2020 16:37:06
User entered 'No (N)'	System	15 Sep 2020 16:37:06

US3012171

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:47:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-09-15T11:37:01', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '80a88349-15f3-4df6-81a9-76b399417e09'	System	15 Sep 2020 16:37:06
User entered '15 Sep 2020 11:37'	System	15 Sep 2020 16:37:06

US3012171

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:47:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
User entered '15 Sep 2020 11:21'	System	15 Sep 2020 16:35:07

US3012171

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:47:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
User entered '15 Sep 2020 13:51'	System	15 Sep 2020 16:35:07

US3012171

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
Data entry locked.	System	15 Sep 2020 16:35:07
User entered 'Day 1, after vaccination (at home)'	System	15 Sep 2020 16:35:07

US3012171

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:47:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-09-15T20:45:21', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '4f686881-3785-4e93-b9af-74f128c12cbc'	System	16 Sep 2020 01:45:54
User entered 'Yes (Y)'	System	16 Sep 2020 01:45:54

US3012171

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:47:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-09-15T20:45:38', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '4f686881-3785-4e93-b9af-74f128c12cbc'	System	16 Sep 2020 01:45:54
User entered '97.6'	System	16 Sep 2020 01:45:54

US3012171

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:47:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-09-15T20:45:42', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '4f686881-3785-4e93-b9af-74f128c12cbc'	System	16 Sep 2020 01:45:54
User entered 'No (N)'	System	16 Sep 2020 01:45:54

US3012171

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:47:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-09-15T20:45:44', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '4f686881-3785-4e93-b9af-74f128c12cbc'	System	16 Sep 2020 01:45:54
User entered '15 Sep 2020 20:45'	System	16 Sep 2020 01:45:54

US3012171

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:47:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
User entered '15 Sep 2020 14:46'	System	15 Sep 2020 16:35:07

US3012171

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:47:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
User entered '16 Sep 2020 11:59'	System	15 Sep 2020 16:35:07

US3012171

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
Data entry locked.	System	15 Sep 2020 16:35:07
User entered 'Day 2'	System	15 Sep 2020 16:35:07

US3012171

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:47:42

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-09-16T14:22:36', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '82ea511c-2799-4c63-a976-94566f843202'	System	16 Sep 2020 19:22:55
User entered 'Yes (Y)'	System	16 Sep 2020 19:22:55

US3012171

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:47:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-09-16T14:22:43', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '82ea511c-2799-4c63-a976-94566f843202'	System	16 Sep 2020 19:22:55
User entered '98.1'	System	16 Sep 2020 19:22:55

US3012171

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:47:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-09-16T14:22:46', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '82ea511c-2799-4c63-a976-94566f843202'	System	16 Sep 2020 19:22:55
User entered 'No (N)'	System	16 Sep 2020 19:22:55

US3012171

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:47:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-09-16T14:22:51', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '82ea511c-2799-4c63-a976-94566f843202'	System	16 Sep 2020 19:22:55
User entered '16 Sep 2020 14:22'	System	16 Sep 2020 19:22:55

US3012171

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:47:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
User entered '16 Sep 2020 12:00'	System	15 Sep 2020 16:35:07

US3012171

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:47:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
User entered '17 Sep 2020 11:59'	System	15 Sep 2020 16:35:07

US3012171

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
Data entry locked.	System	15 Sep 2020 16:35:07
User entered 'Day 3'	System	15 Sep 2020 16:35:07

US3012171

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:47:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-09-17T23:13:14', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: 'bcf4513a-f82e-4fa4-88fc-3ea90eb73ca6'	System	18 Sep 2020 04:13:34
User entered 'Yes (Y)'	System	18 Sep 2020 04:13:34

US3012171

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:47:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-09-17T23:13:21', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: 'bcf4513a-f82e-4fa4-88fc-3ea90eb73ca6'	System	18 Sep 2020 04:13:34
User entered '97.4'	System	18 Sep 2020 04:13:34

US3012171

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:47:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-09-17T23:13:23', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: 'bcf4513a-f82e-4fa4-88fc-3ea90eb73ca6'	System	18 Sep 2020 04:13:34
User entered 'No (N)'	System	18 Sep 2020 04:13:34

US3012171

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:47:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-09-17T23:13:28', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: 'bcf4513a-f82e-4fa4-88fc-3ea90eb73ca6'	System	18 Sep 2020 04:13:34
User entered '17 Sep 2020 23:13'	System	18 Sep 2020 04:13:34

US3012171

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:47:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
User entered '17 Sep 2020 12:00'	System	15 Sep 2020 16:35:07

US3012171

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:47:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
User entered '18 Sep 2020 11:59'	System	15 Sep 2020 16:35:07

US3012171

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
Data entry locked.	System	15 Sep 2020 16:35:07
User entered 'Day 4'	System	15 Sep 2020 16:35:07

US3012171

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:47:42

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-09-19T01:13:27', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '18d2c6ba-59e1-4869-af4a-6f9d7570b664'	System	19 Sep 2020 06:13:43
User entered 'Yes (Y)'	System	19 Sep 2020 06:13:43

US3012171

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:47:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-09-19T01:13:33', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '18d2c6ba-59e1-4869-af4a-6f9d7570b664'	System	19 Sep 2020 06:13:43
User entered '97.4'	System	19 Sep 2020 06:13:43

US3012171

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:47:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-09-19T01:13:36', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '18d2c6ba-59e1-4869-af4a-6f9d7570b664'	System	19 Sep 2020 06:13:43
User entered 'No (N)'	System	19 Sep 2020 06:13:43

US3012171

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:47:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-09-19T01:13:38', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '18d2c6ba-59e1-4869-af4a-6f9d7570b664'	System	19 Sep 2020 06:13:43
User entered '19 Sep 2020 01:13'	System	19 Sep 2020 06:13:43

US3012171

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:47:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
User entered '18 Sep 2020 12:00'	System	15 Sep 2020 16:35:07

US3012171

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:47:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
User entered '19 Sep 2020 11:59'	System	15 Sep 2020 16:35:07

US3012171

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
Data entry locked.	System	15 Sep 2020 16:35:07
User entered 'Day 5'	System	15 Sep 2020 16:35:07

US3012171

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:47:42

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-09-20T00:00:01', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: 'e70692c0-eb8b-42cc-95ab-1b4452b951e4'	System	20 Sep 2020 05:00:24
User entered 'Yes (Y)'	System	20 Sep 2020 05:00:24

US3012171

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:47:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-09-20T00:00:08', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: 'e70692c0-eb8b-42cc-95ab-1b4452b951e4' User entered '97.3'	System	20 Sep 2020 05:00:24
	System	20 Sep 2020 05:00:24

US3012171

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:47:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-09-20T00:00:11', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: 'e70692c0-eb8b-42cc-95ab-1b4452b951e4'	System	20 Sep 2020 05:00:24
User entered 'No (N)'	System	20 Sep 2020 05:00:24

US3012171

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:47:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-09-20T00:00:14', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: 'e70692c0-eb8b-42cc-95ab-1b4452b951e4'	System	20 Sep 2020 05:00:24
User entered '20 Sep 2020 00:00'	System	20 Sep 2020 05:00:24

US3012171

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:47:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
User entered '19 Sep 2020 12:00'	System	15 Sep 2020 16:35:07

US3012171

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:47:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
User entered '20 Sep 2020 11:59'	System	15 Sep 2020 16:35:07

US3012171

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
Data entry locked.	System	15 Sep 2020 16:35:07
User entered 'Day 6'	System	15 Sep 2020 16:35:07

US3012171

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:47:42

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-09-20T22:08:48', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: 'bc5f3212-681c-405e-85e2-79fe500f4f9f'	System	21 Sep 2020 03:09:05
User entered 'Yes (Y)'	System	21 Sep 2020 03:09:05

US3012171

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:47:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-09-20T22:08:54', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: 'bc5f3212-681c-405e-85e2-79fe500f4f9f'	System	21 Sep 2020 03:09:05
User entered '97.5'	System	21 Sep 2020 03:09:05

US3012171

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:47:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-09-20T22:08:57', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: 'bc5f3212-681c-405e-85e2-79fe500f4f9f'	System	21 Sep 2020 03:09:05
User entered 'No (N)'	System	21 Sep 2020 03:09:05

US3012171

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:47:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-09-20T22:08:59', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: 'bc5f3212-681c-405e-85e2-79fe500f4f9f'	System	21 Sep 2020 03:09:05
User entered '20 Sep 2020 22:08'	System	21 Sep 2020 03:09:05

US3012171

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:47:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
User entered '20 Sep 2020 12:00'	System	15 Sep 2020 16:35:07

US3012171

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:47:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
User entered '21 Sep 2020 11:59'	System	15 Sep 2020 16:35:07

US3012171

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
Data entry locked.	System	15 Sep 2020 16:35:07
User entered 'Day 7'	System	15 Sep 2020 16:35:07

US3012171

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:47:42

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-09-22T10:42:03', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: 'b5db1b09-a570-4f2b-9f34-031464d31ec2'	System	22 Sep 2020 15:42:23
User entered 'Yes (Y)'	System	22 Sep 2020 15:42:23

US3012171

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:47:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-09-22T10:42:11', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: 'b5db1b09-a570-4f2b-9f34-031464d31ec2'	System	22 Sep 2020 15:42:23
User entered '97.6'	System	22 Sep 2020 15:42:23

US3012171

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:47:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-09-22T10:42:14', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: 'b5db1b09-a570-4f2b-9f34-031464d31ec2'	System	22 Sep 2020 15:42:23
User entered 'No (N)'	System	22 Sep 2020 15:42:23

US3012171

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:47:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-09-22T10:42:17', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: 'b5db1b09-a570-4f2b-9f34-031464d31ec2'	System	22 Sep 2020 15:42:23
User entered '22 Sep 2020 10:42'	System	22 Sep 2020 15:42:23

US3012171

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:47:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
User entered '21 Sep 2020 12:00'	System	15 Sep 2020 16:35:07

US3012171

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:47:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
User entered '22 Sep 2020 11:59'	System	15 Sep 2020 16:35:07

US3012171

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
Data entry locked.	System	15 Sep 2020 16:35:07
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	15 Sep 2020 16:35:07

US3012171

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:47:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-09-15T11:37:10', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: 'e1b67d85-9c4b-4d68-b8c7-5310857b964a'	System	15 Sep 2020 16:37:48
User entered 'None (1)'	System	15 Sep 2020 16:37:48

US3012171

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:47:42

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-09-15T11:37:32', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: 'e1b67d85-9c4b-4d68-b8c7-5310857b964a'	System	15 Sep 2020 16:37:48
User entered 'No (N)'	System	15 Sep 2020 16:37:48

US3012171

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:47:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-09-15T11:37:35', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: 'e1b67d85-9c4b-4d68-b8c7-5310857b964a'	System	15 Sep 2020 16:37:48
User entered 'No (N)'	System	15 Sep 2020 16:37:48

US3012171

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:47:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-09-15T11:37:40', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: 'e1b67d85-9c4b-4d68-b8c7-5310857b964a'	System	15 Sep 2020 16:37:48
User entered 'None (1)'	System	15 Sep 2020 16:37:48

US3012171

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:47:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-09-15T11:37:43', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: 'e1b67d85-9c4b-4d68-b8c7-5310857b964a'	System	15 Sep 2020 16:37:48
User entered '15 Sep 2020 11:37'	System	15 Sep 2020 16:37:48

US3012171

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:47:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
User entered '15 Sep 2020 11:21'	System	15 Sep 2020 16:35:07

US3012171

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:47:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
User entered '15 Sep 2020 13:51'	System	15 Sep 2020 16:35:07

US3012171

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
Data entry locked.	System	15 Sep 2020 16:35:07
User entered 'Day 1, after vaccination (at home)'	System	15 Sep 2020 16:35:07

US3012171

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:47:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-09-15T20:45:52', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '66b1a1cf-7496-4e8e-9533-48e658cbc596'	System	16 Sep 2020 01:46:08
User entered 'Does not interfere with activity (2)'	System	16 Sep 2020 01:46:08

US3012171

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:47:42

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-09-15T20:45:55', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '66b1a1cf-7496-4e8e-9533-48e658cbc596'	System	16 Sep 2020 01:46:08
User entered 'No (N)'	System	16 Sep 2020 01:46:08

US3012171

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:47:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-09-15T20:45:58', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '66b1a1cf-7496-4e8e-9533-48e658cbc596'	System	16 Sep 2020 01:46:08
User entered 'No (N)'	System	16 Sep 2020 01:46:08

US3012171

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:47:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-09-15T20:46:01', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '66b1a1cf-7496-4e8e-9533-48e658cbc596'	System	16 Sep 2020 01:46:08
User entered 'None (1)'	System	16 Sep 2020 01:46:08

US3012171

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:47:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-09-15T20:46:05', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '66b1a1cf-7496-4e8e-9533-48e658cbc596'	System	16 Sep 2020 01:46:08
User entered '15 Sep 2020 20:46'	System	16 Sep 2020 01:46:08

US3012171

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:47:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
User entered '15 Sep 2020 14:46'	System	15 Sep 2020 16:35:07

US3012171

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:47:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
User entered '16 Sep 2020 11:59'	System	15 Sep 2020 16:35:07

US3012171

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
Data entry locked.	System	15 Sep 2020 16:35:07
User entered 'Day 2'	System	15 Sep 2020 16:35:07

US3012171

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:47:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-09-16T14:23:01', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '2900373e-ac0f-48fe-9beb-dd58cb7cc2ea'	System	16 Sep 2020 19:23:20
User entered 'Does not interfere with activity (2)'	System	16 Sep 2020 19:23:20

US3012171

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:47:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-09-16T14:23:05', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '2900373e-ac0f-48fe-9beb-dd58cb7cc2ea'	System	16 Sep 2020 19:23:20
User entered 'No (N)'	System	16 Sep 2020 19:23:20

US3012171

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:47:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-09-16T14:23:09', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '2900373e-ac0f-48fe-9beb-dd58cb7cc2ea'	System	16 Sep 2020 19:23:20
User entered 'No (N)'	System	16 Sep 2020 19:23:20

US3012171

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:47:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-09-16T14:23:14', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '2900373e-ac0f-48fe-9beb-dd58cb7cc2ea'	System	16 Sep 2020 19:23:20
User entered 'None (1)'	System	16 Sep 2020 19:23:20

US3012171

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:47:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-09-16T14:23:17', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '2900373e-ac0f-48fe-9beb-dd58cb7cc2ea'	System	16 Sep 2020 19:23:20
User entered '16 Sep 2020 14:23'	System	16 Sep 2020 19:23:20

US3012171

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:47:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
User entered '16 Sep 2020 12:00'	System	15 Sep 2020 16:35:07

US3012171

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:47:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
User entered '17 Sep 2020 11:59'	System	15 Sep 2020 16:35:07

US3012171

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
Data entry locked.	System	15 Sep 2020 16:35:07
User entered 'Day 3'	System	15 Sep 2020 16:35:07

US3012171

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:47:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-09-17T23:13:34', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: 'be251477-e758-4b44-9b23-a5f2a3f9ad0d'	System	18 Sep 2020 04:13:50
User entered 'Does not interfere with activity (2)'	System	18 Sep 2020 04:13:50

US3012171

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:47:42

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-09-17T23:13:38', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: 'be251477-e758-4b44-9b23-a5f2a3f9ad0d'	System	18 Sep 2020 04:13:50
User entered 'No (N)'	System	18 Sep 2020 04:13:50

US3012171

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:47:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-09-17T23:13:41', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: 'be251477-e758-4b44-9b23-a5f2a3f9ad0d'	System	18 Sep 2020 04:13:50
User entered 'No (N)'	System	18 Sep 2020 04:13:50

US3012171

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:47:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-09-17T23:13:45', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: 'be251477-e758-4b44-9b23-a5f2a3f9ad0d'	System	18 Sep 2020 04:13:50
User entered 'None (1)'	System	18 Sep 2020 04:13:50

US3012171

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:47:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-09-17T23:13:47', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: 'be251477-e758-4b44-9b23-a5f2a3f9ad0d'	System	18 Sep 2020 04:13:50
User entered '17 Sep 2020 23:13'	System	18 Sep 2020 04:13:50

US3012171

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:47:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
User entered '17 Sep 2020 12:00'	System	15 Sep 2020 16:35:07

US3012171

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:47:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
User entered '18 Sep 2020 11:59'	System	15 Sep 2020 16:35:07

US3012171

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
Data entry locked.	System	15 Sep 2020 16:35:07
User entered 'Day 4'	System	15 Sep 2020 16:35:07

US3012171

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:47:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-09-19T01:13:44', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '85c24dd9-0e82-4eb2-8ad4-bacff2f23298'	System	19 Sep 2020 06:13:58
User entered 'Does not interfere with activity (2)'	System	19 Sep 2020 06:13:58

US3012171

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:47:42

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-09-19T01:13:47', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '85c24dd9-0e82-4eb2-8ad4-bacff2f23298'	System	19 Sep 2020 06:13:58
User entered 'No (N)'	System	19 Sep 2020 06:13:58

US3012171

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:47:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-09-19T01:13:49', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '85c24dd9-0e82-4eb2-8ad4-bacff2f23298'	System	19 Sep 2020 06:13:58
User entered 'No (N)'	System	19 Sep 2020 06:13:58

US3012171

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:47:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-09-19T01:13:52', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '85c24dd9-0e82-4eb2-8ad4-bacff2f23298'	System	19 Sep 2020 06:13:58
User entered 'None (1)'	System	19 Sep 2020 06:13:58

US3012171

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:47:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-09-19T01:13:54', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '85c24dd9-0e82-4eb2-8ad4-bacff2f23298'	System	19 Sep 2020 06:13:58
User entered '19 Sep 2020 01:13'	System	19 Sep 2020 06:13:58

US3012171

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:47:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
User entered '18 Sep 2020 12:00'	System	15 Sep 2020 16:35:07

US3012171

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:47:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
User entered '19 Sep 2020 11:59'	System	15 Sep 2020 16:35:07

US3012171

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
Data entry locked.	System	15 Sep 2020 16:35:07
User entered 'Day 5'	System	15 Sep 2020 16:35:07

US3012171

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:47:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-09-20T00:00:18', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: 'b3cac5ff-0ee3-4e5c-82c0-e0c452e4c23b'	System	20 Sep 2020 05:00:31
User entered 'Does not interfere with activity (2)'	System	20 Sep 2020 05:00:31

US3012171

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:47:42

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-09-20T00:00:21', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: 'b3cac5ff-0ee3-4e5c-82c0-e0c452e4c23b'	System	20 Sep 2020 05:00:31
User entered 'No (N)'	System	20 Sep 2020 05:00:31

US3012171

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:47:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-09-20T00:00:24', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: 'b3cac5ff-0ee3-4e5c-82c0-e0c452e4c23b'	System	20 Sep 2020 05:00:31
User entered 'No (N)'	System	20 Sep 2020 05:00:31

US3012171

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:47:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-09-20T00:00:26', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: 'b3cac5ff-0ee3-4e5c-82c0-e0c452e4c23b'	System	20 Sep 2020 05:00:31
User entered 'None (1)'	System	20 Sep 2020 05:00:31

US3012171

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:47:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-09-20T00:00:29', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: 'b3cac5ff-0ee3-4e5c-82c0-e0c452e4c23b'	System	20 Sep 2020 05:00:31
User entered '20 Sep 2020 00:00'	System	20 Sep 2020 05:00:31

US3012171

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:47:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
User entered '19 Sep 2020 12:00'	System	15 Sep 2020 16:35:07

US3012171

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:47:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
User entered '20 Sep 2020 11:59'	System	15 Sep 2020 16:35:07

US3012171

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
Data entry locked.	System	15 Sep 2020 16:35:07
User entered 'Day 6'	System	15 Sep 2020 16:35:07

US3012171

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:47:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-09-20T22:09:03', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '57076d40-52ea-441e-bb2b-5f2b7e944ceb'	System	21 Sep 2020 03:09:17
User entered 'None (1)'	System	21 Sep 2020 03:09:17

US3012171

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:47:42

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-09-20T22:09:06', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '57076d40-52ea-441e-bb2b-5f2b7e944ceb'	System	21 Sep 2020 03:09:17
User entered 'No (N)'	System	21 Sep 2020 03:09:17

US3012171

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:47:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-09-20T22:09:09', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '57076d40-52ea-441e-bb2b-5f2b7e944ceb'	System	21 Sep 2020 03:09:17
User entered 'No (N)'	System	21 Sep 2020 03:09:17

US3012171

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:47:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-09-20T22:09:11', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '57076d40-52ea-441e-bb2b-5f2b7e944ceb'	System	21 Sep 2020 03:09:17
User entered 'None (1)'	System	21 Sep 2020 03:09:17

US3012171

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:47:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-09-20T22:09:13', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '57076d40-52ea-441e-bb2b-5f2b7e944ceb'	System	21 Sep 2020 03:09:17
User entered '20 Sep 2020 22:09'	System	21 Sep 2020 03:09:17

US3012171

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:47:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
User entered '20 Sep 2020 12:00'	System	15 Sep 2020 16:35:07

US3012171

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:47:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
User entered '21 Sep 2020 11:59'	System	15 Sep 2020 16:35:07

US3012171

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
Data entry locked.	System	15 Sep 2020 16:35:07
User entered 'Day 7'	System	15 Sep 2020 16:35:07

US3012171

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:47:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-09-22T10:42:23', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '65edad2d-d0b4-4885-9fdc-19045cc1d8dc'	System	22 Sep 2020 15:42:39
User entered 'None (1)'	System	22 Sep 2020 15:42:39

US3012171

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:47:42

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-09-22T10:42:25', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '65edad2d-d0b4-4885-9fdc-19045cc1d8dc'	System	22 Sep 2020 15:42:39
User entered 'No (N)'	System	22 Sep 2020 15:42:39

US3012171

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:47:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-09-22T10:42:28', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '65edad2d-d0b4-4885-9fdc-19045cc1d8dc'	System	22 Sep 2020 15:42:39
User entered 'No (N)'	System	22 Sep 2020 15:42:39

US3012171

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:47:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-09-22T10:42:30', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '65edad2d-d0b4-4885-9fdc-19045cc1d8dc'	System	22 Sep 2020 15:42:39
User entered 'None (1)'	System	22 Sep 2020 15:42:39

US3012171

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:47:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-09-22T10:42:32', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '65edad2d-d0b4-4885-9fdc-19045cc1d8dc'	System	22 Sep 2020 15:42:39
User entered '22 Sep 2020 10:42'	System	22 Sep 2020 15:42:39

US3012171

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:47:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
User entered '21 Sep 2020 12:00'	System	15 Sep 2020 16:35:07

US3012171

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:47:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
User entered '22 Sep 2020 11:59'	System	15 Sep 2020 16:35:07

US3012171

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
Data entry locked.	System	15 Sep 2020 16:35:07
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	15 Sep 2020 16:35:07

US3012171

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:47:42

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-09-15T11:37:48', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: 'bbd40e95-15b1-4384-8641-3586b933da48'	System	15 Sep 2020 16:38:12
User entered 'None (0)'	System	15 Sep 2020 16:38:12

US3012171

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:47:42

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-09-15T11:37:50', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: 'bbd40e95-15b1-4384-8641-3586b933da48'	System	15 Sep 2020 16:38:12
User entered 'None (0)'	System	15 Sep 2020 16:38:12

US3012171

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:47:42

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-09-15T11:37:53', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: 'bbd40e95-15b1-4384-8641-3586b933da48'	System	15 Sep 2020 16:38:12
User entered 'None (0)'	System	15 Sep 2020 16:38:12

US3012171

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:47:42

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-09-15T11:37:56', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: 'bbd40e95-15b1-4384-8641-3586b933da48'	System	15 Sep 2020 16:38:12
User entered 'None (0)'	System	15 Sep 2020 16:38:12

US3012171

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:47:42

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-09-15T11:37:59', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: 'bbd40e95-15b1-4384-8641-3586b933da48'	System	15 Sep 2020 16:38:12
User entered 'None (0)'	System	15 Sep 2020 16:38:12

US3012171

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:47:42

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-09-15T11:38:01', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: 'bbd40e95-15b1-4384-8641-3586b933da48'	System	15 Sep 2020 16:38:12
User entered 'None (0)'	System	15 Sep 2020 16:38:12

US3012171

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:47:42

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)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-09-15T11:38:06', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: 'bbd40e95-15b1-4384-8641-3586b933da48'	System	15 Sep 2020 16:38:12
User entered 'No (N)'	System	15 Sep 2020 16:38:12

US3012171

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:47:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-09-15T11:38:09', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: 'bbd40e95-15b1-4384-8641-3586b933da48'	System	15 Sep 2020 16:38:12
User entered '15 Sep 2020 11:38'	System	15 Sep 2020 16:38:12

US3012171

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:47:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
User entered '15 Sep 2020 11:21'	System	15 Sep 2020 16:35:07

US3012171

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:47:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
User entered '15 Sep 2020 13:51'	System	15 Sep 2020 16:35:07

US3012171

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
Data entry locked.	System	15 Sep 2020 16:35:07
User entered 'Day 1, after vaccination (at home)'	System	15 Sep 2020 16:35:07

US3012171

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:47:42

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-09-15T20:46:09', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: 'e6f5364e-d9b0-4b44-a14b-c375710d8cf6'	System	16 Sep 2020 01:46:29
User entered 'None (0)'	System	16 Sep 2020 01:46:29

US3012171

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:47:42

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-09-15T20:46:11', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: 'e6f5364e-d9b0-4b44-a14b-c375710d8cf6'	System	16 Sep 2020 01:46:29
User entered 'None (0)'	System	16 Sep 2020 01:46:29

US3012171

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:47:42

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-09-15T20:46:14', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: 'e6f5364e-d9b0-4b44-a14b-c375710d8cf6'	System	16 Sep 2020 01:46:29
User entered 'None (0)'	System	16 Sep 2020 01:46:29

US3012171

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:47:42

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-09-15T20:46:16', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: 'e6f5364e-d9b0-4b44-a14b-c375710d8cf6'	System	16 Sep 2020 01:46:29
User entered 'None (0)'	System	16 Sep 2020 01:46:29

US3012171

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:47:42

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-09-15T20:46:19', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: 'e6f5364e-d9b0-4b44-a14b-c375710d8cf6'	System	16 Sep 2020 01:46:29
User entered 'None (0)'	System	16 Sep 2020 01:46:29

US3012171

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:47:42

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-09-15T20:46:21', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: 'e6f5364e-d9b0-4b44-a14b-c375710d8cf6'	System	16 Sep 2020 01:46:29
User entered 'None (0)'	System	16 Sep 2020 01:46:29

US3012171

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:47:42

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)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-09-15T20:46:24', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: 'e6f5364e-d9b0-4b44-a14b-c375710d8cf6'	System	16 Sep 2020 01:46:29
User entered 'No (N)'	System	16 Sep 2020 01:46:29

US3012171

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:47:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-09-15T20:46:27', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: 'e6f5364e-d9b0-4b44-a14b-c375710d8cf6'	System	16 Sep 2020 01:46:29
User entered '15 Sep 2020 20:46'	System	16 Sep 2020 01:46:29

US3012171

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:47:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
User entered '15 Sep 2020 14:46'	System	15 Sep 2020 16:35:07

US3012171

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:47:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
User entered '16 Sep 2020 11:59'	System	15 Sep 2020 16:35:07

US3012171

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
Data entry locked.	System	15 Sep 2020 16:35:07
User entered 'Day 2'	System	15 Sep 2020 16:35:07

US3012171

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:47:42

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-09-16T14:23:24', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: 'b3f3408b-ea8d-4f05-94ac-7cbb955ec683'	System	16 Sep 2020 19:23:53
User entered 'No interference with activity (1)'	System	16 Sep 2020 19:23:53

US3012171

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:47:42

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-09-16T14:23:28', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: 'b3f3408b-ea8d-4f05-94ac-7cbb955ec683'	System	16 Sep 2020 19:23:53
User entered 'No interference with activity (1)'	System	16 Sep 2020 19:23:53

US3012171

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:47:42

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-09-16T14:23:32', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: 'b3f3408b-ea8d-4f05-94ac-7cbb955ec683'	System	16 Sep 2020 19:23:53
User entered 'No interference with activity (1)'	System	16 Sep 2020 19:23:53

US3012171

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:47:42

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-09-16T14:23:34', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: 'b3f3408b-ea8d-4f05-94ac-7cbb955ec683'	System	16 Sep 2020 19:23:53
User entered 'No interference with activity (1)'	System	16 Sep 2020 19:23:53

US3012171

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:47:42

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-09-16T14:23:37', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: 'b3f3408b-ea8d-4f05-94ac-7cbb955ec683'	System	16 Sep 2020 19:23:53
User entered 'None (0)'	System	16 Sep 2020 19:23:53

US3012171

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:47:42

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-09-16T14:23:41', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: 'b3f3408b-ea8d-4f05-94ac-7cbb955ec683'	System	16 Sep 2020 19:23:53
User entered 'None (0)'	System	16 Sep 2020 19:23:53

US3012171

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:47:42

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)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-09-16T14:23:46', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: 'b3f3408b-ea8d-4f05-94ac-7cbb955ec683'	System	16 Sep 2020 19:23:53
User entered 'No (N)'	System	16 Sep 2020 19:23:53

US3012171

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:47:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-09-16T14:23:48', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: 'b3f3408b-ea8d-4f05-94ac-7cbb955ec683'	System	16 Sep 2020 19:23:53
User entered '16 Sep 2020 14:23'	System	16 Sep 2020 19:23:53

US3012171

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:47:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
User entered '16 Sep 2020 12:00'	System	15 Sep 2020 16:35:07

US3012171

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:47:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
User entered '17 Sep 2020 11:59'	System	15 Sep 2020 16:35:07

US3012171

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
Data entry locked.	System	15 Sep 2020 16:35:07
User entered 'Day 3'	System	15 Sep 2020 16:35:07

US3012171

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:47:42

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-09-17T23:13:53', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '47536ca8-c4ff-4b72-9dfb-8d5bcf874309'	System	18 Sep 2020 04:14:14
User entered 'No interference with activity (1)'	System	18 Sep 2020 04:14:14

US3012171

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:47:42

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-09-17T23:13:56', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '47536ca8-c4ff-4b72-9dfb-8d5bcf874309'	System	18 Sep 2020 04:14:14
User entered 'No interference with activity (1)'	System	18 Sep 2020 04:14:14

US3012171

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:47:42

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-09-17T23:14:00', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '47536ca8-c4ff-4b72-9dfb-8d5bcf874309'	System	18 Sep 2020 04:14:14
User entered 'No interference with activity (1)'	System	18 Sep 2020 04:14:14

US3012171

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:47:42

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-09-17T23:14:02', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '47536ca8-c4ff-4b72-9dfb-8d5bcf874309'	System	18 Sep 2020 04:14:14
User entered 'None (0)'	System	18 Sep 2020 04:14:14

US3012171

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:47:42

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-09-17T23:14:04', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '47536ca8-c4ff-4b72-9dfb-8d5bcf874309'	System	18 Sep 2020 04:14:14
User entered 'None (0)'	System	18 Sep 2020 04:14:14

US3012171

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:47:42

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-09-17T23:14:07', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '47536ca8-c4ff-4b72-9dfb-8d5bcf874309'	System	18 Sep 2020 04:14:14
User entered 'None (0)'	System	18 Sep 2020 04:14:14

US3012171

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:47:42

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)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-09-17T23:14:10', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '47536ca8-c4ff-4b72-9dfb-8d5bcf874309'	System	18 Sep 2020 04:14:14
User entered 'No (N)'	System	18 Sep 2020 04:14:14

US3012171

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:47:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-09-17T23:14:12', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '47536ca8-c4ff-4b72-9dfb-8d5bcf874309'	System	18 Sep 2020 04:14:14
User entered '17 Sep 2020 23:14'	System	18 Sep 2020 04:14:14

US3012171

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:47:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
User entered '17 Sep 2020 12:00'	System	15 Sep 2020 16:35:07

US3012171

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:47:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
User entered '18 Sep 2020 11:59'	System	15 Sep 2020 16:35:07

US3012171

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
Data entry locked.	System	15 Sep 2020 16:35:07
User entered 'Day 4'	System	15 Sep 2020 16:35:07

US3012171

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:47:42

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-09-19T01:14:03', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '4015807c-64c6-4fe2-b3e6-4736e75b1409'	System	19 Sep 2020 06:14:31
User entered 'None (0)'	System	19 Sep 2020 06:14:31

US3012171

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:47:42

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-09-19T01:14:07', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '4015807c-64c6-4fe2-b3e6-4736e75b1409'	System	19 Sep 2020 06:14:31
User entered 'No interference with activity (1)'	System	19 Sep 2020 06:14:31

US3012171

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:47:42

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-09-19T01:14:13', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '4015807c-64c6-4fe2-b3e6-4736e75b1409'	System	19 Sep 2020 06:14:31
User entered 'No interference with activity (1)'	System	19 Sep 2020 06:14:31

US3012171

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:47:42

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-09-19T01:14:15', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '4015807c-64c6-4fe2-b3e6-4736e75b1409'	System	19 Sep 2020 06:14:31
User entered 'None (0)'	System	19 Sep 2020 06:14:31

US3012171

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:47:42

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-09-19T01:14:20', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '4015807c-64c6-4fe2-b3e6-4736e75b1409'	System	19 Sep 2020 06:14:31
User entered 'None (0)'	System	19 Sep 2020 06:14:31

US3012171

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:47:42

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-09-19T01:14:22', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '4015807c-64c6-4fe2-b3e6-4736e75b1409'	System	19 Sep 2020 06:14:31
User entered 'None (0)'	System	19 Sep 2020 06:14:31

US3012171

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:47:42

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)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-09-19T01:14:25', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '4015807c-64c6-4fe2-b3e6-4736e75b1409'	System	19 Sep 2020 06:14:31
User entered 'No (N)'	System	19 Sep 2020 06:14:31

US3012171

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:47:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-09-19T01:14:27', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '4015807c-64c6-4fe2-b3e6-4736e75b1409'	System	19 Sep 2020 06:14:31
User entered '19 Sep 2020 01:14'	System	19 Sep 2020 06:14:31

US3012171

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:47:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
User entered '18 Sep 2020 12:00'	System	15 Sep 2020 16:35:07

US3012171

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:47:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
User entered '19 Sep 2020 11:59'	System	15 Sep 2020 16:35:07

US3012171

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
Data entry locked.	System	15 Sep 2020 16:35:07
User entered 'Day 5'	System	15 Sep 2020 16:35:07

US3012171

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:47:42

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-09-20T00:00:33', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '7a6f52ea-524f-4803-8a72-2db7dda1b5ce'	System	20 Sep 2020 05:00:54
User entered 'None (0)'	System	20 Sep 2020 05:00:54

US3012171

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:47:42

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-09-20T00:00:35', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '7a6f52ea-524f-4803-8a72-2db7dda1b5ce'	System	20 Sep 2020 05:00:54
User entered 'No interference with activity (1)'	System	20 Sep 2020 05:00:54

US3012171

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:47:42

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-09-20T00:00:39', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '7a6f52ea-524f-4803-8a72-2db7dda1b5ce'	System	20 Sep 2020 05:00:54
User entered 'No interference with activity (1)'	System	20 Sep 2020 05:00:54

US3012171

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:47:42

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-09-20T00:00:41', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '7a6f52ea-524f-4803-8a72-2db7dda1b5ce'	System	20 Sep 2020 05:00:54
User entered 'None (0)'	System	20 Sep 2020 05:00:54

US3012171

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:47:42

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-09-20T00:00:43', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '7a6f52ea-524f-4803-8a72-2db7dda1b5ce'	System	20 Sep 2020 05:00:54
User entered 'None (0)'	System	20 Sep 2020 05:00:54

US3012171

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:47:42

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-09-20T00:00:45', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '7a6f52ea-524f-4803-8a72-2db7dda1b5ce'	System	20 Sep 2020 05:00:54
User entered 'None (0)'	System	20 Sep 2020 05:00:54

US3012171

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:47:42

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)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-09-20T00:00:48', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '7a6f52ea-524f-4803-8a72-2db7dda1b5ce'	System	20 Sep 2020 05:00:54
User entered 'No (N)'	System	20 Sep 2020 05:00:54

US3012171

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:47:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-09-20T00:00:50', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '7a6f52ea-524f-4803-8a72-2db7dda1b5ce'	System	20 Sep 2020 05:00:54
User entered '20 Sep 2020 00:00'	System	20 Sep 2020 05:00:54

US3012171

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:47:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
User entered '19 Sep 2020 12:00'	System	15 Sep 2020 16:35:07

US3012171

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:47:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
User entered '20 Sep 2020 11:59'	System	15 Sep 2020 16:35:07

US3012171

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
Data entry locked.	System	15 Sep 2020 16:35:07
User entered 'Day 6'	System	15 Sep 2020 16:35:07

US3012171

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:47:42

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-09-20T22:09:17', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: 'aa808fe0-5bb8-4f87-b152-d59b5e2b9c82'	System	21 Sep 2020 03:09:38
User entered 'None (0)'	System	21 Sep 2020 03:09:38

US3012171

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:47:42

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-09-20T22:09:22', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: 'aa808fe0-5bb8-4f87-b152-d59b5e2b9c82'	System	21 Sep 2020 03:09:38
User entered 'No interference with activity (1)'	System	21 Sep 2020 03:09:38

US3012171

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:47:42

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-09-20T22:09:24', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: 'aa808fe0-5bb8-4f87-b152-d59b5e2b9c82'	System	21 Sep 2020 03:09:38
User entered 'None (0)'	System	21 Sep 2020 03:09:38

US3012171

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:47:42

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-09-20T22:09:26', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: 'aa808fe0-5bb8-4f87-b152-d59b5e2b9c82'	System	21 Sep 2020 03:09:38
User entered 'None (0)'	System	21 Sep 2020 03:09:38

US3012171

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:47:42

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-09-20T22:09:28', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: 'aa808fe0-5bb8-4f87-b152-d59b5e2b9c82'	System	21 Sep 2020 03:09:38
User entered 'None (0)'	System	21 Sep 2020 03:09:38

US3012171

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:47:42

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-09-20T22:09:30', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: 'aa808fe0-5bb8-4f87-b152-d59b5e2b9c82'	System	21 Sep 2020 03:09:38
User entered 'None (0)'	System	21 Sep 2020 03:09:38

US3012171

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:47:42

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)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-09-20T22:09:33', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: 'aa808fe0-5bb8-4f87-b152-d59b5e2b9c82'	System	21 Sep 2020 03:09:38
User entered 'No (N)'	System	21 Sep 2020 03:09:38

US3012171

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:47:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-09-20T22:09:35', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: 'aa808fe0-5bb8-4f87-b152-d59b5e2b9c82'	System	21 Sep 2020 03:09:38
User entered '20 Sep 2020 22:09'	System	21 Sep 2020 03:09:38

US3012171

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:47:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
User entered '20 Sep 2020 12:00'	System	15 Sep 2020 16:35:07

US3012171

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:47:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
User entered '21 Sep 2020 11:59'	System	15 Sep 2020 16:35:07

US3012171

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
Data entry locked.	System	15 Sep 2020 16:35:07
User entered 'Day 7'	System	15 Sep 2020 16:35:07

US3012171

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:47:42

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-09-22T10:42:50', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '8fe7d180-4004-4b39-be62-41acea4a793e'	System	22 Sep 2020 15:43:09
User entered 'None (0)'	System	22 Sep 2020 15:43:09

US3012171

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:47:42

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-09-22T10:42:51', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '8fe7d180-4004-4b39-be62-41acea4a793e'	System	22 Sep 2020 15:43:09
User entered 'None (0)'	System	22 Sep 2020 15:43:09

US3012171

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:47:42

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-09-22T10:42:53', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '8fe7d180-4004-4b39-be62-41acea4a793e'	System	22 Sep 2020 15:43:09
User entered 'None (0)'	System	22 Sep 2020 15:43:09

US3012171

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:47:42

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-09-22T10:42:55', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '8fe7d180-4004-4b39-be62-41acea4a793e'	System	22 Sep 2020 15:43:09
User entered 'None (0)'	System	22 Sep 2020 15:43:09

US3012171

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:47:42

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-09-22T10:42:57', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '8fe7d180-4004-4b39-be62-41acea4a793e'	System	22 Sep 2020 15:43:09
User entered 'None (0)'	System	22 Sep 2020 15:43:09

US3012171

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:47:42

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-09-22T10:42:59', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '8fe7d180-4004-4b39-be62-41acea4a793e'	System	22 Sep 2020 15:43:09
User entered 'None (0)'	System	22 Sep 2020 15:43:09

US3012171

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:47:42

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)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-09-22T10:43:01', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '8fe7d180-4004-4b39-be62-41acea4a793e'	System	22 Sep 2020 15:43:09
User entered 'No (N)'	System	22 Sep 2020 15:43:09

US3012171

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:47:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-09-22T10:43:03', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '8fe7d180-4004-4b39-be62-41acea4a793e'	System	22 Sep 2020 15:43:09
User entered '22 Sep 2020 10:43'	System	22 Sep 2020 15:43:09

US3012171

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:47:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
User entered '21 Sep 2020 12:00'	System	15 Sep 2020 16:35:07

US3012171

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:47:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
User entered '22 Sep 2020 11:59'	System	15 Sep 2020 16:35:07

US3012171

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:47:42

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered 'Yes (Y)'	(b) (4) Tambra Dora (b) (4)	25 Sep 2020 19:23:59

US3012171

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:47:42

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered '25 Sep 2020'	Tambra Dora (b) (4)	25 Sep 2020 19:23:59

US3012171

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:47:42

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered 'Contact Made (CONTACT MADE)'	Tambra Dora (b) (4)	25 Sep 2020 19:23:59

US3012171

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:47:42

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered empty.	(b) (4) Tambra Dora (b) (4)	25 Sep 2020 19:23:59

US3012171

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:47:42

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered 'Yes (Y)'	Tambra Dora (b) (4)	25 Sep 2020 19:24:04

US3012171

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:47:42

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User entered 'I'	System	25 Sep 2020 19:24:04

US3012171

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:47:42

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered 'Yes (Y)'	Katherine Davis (b) (4)	29 Sep 2020 23:36:23

US3012171

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:47:42

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered '29 Sep 2020'	Katherine Davis (b) (4)	29 Sep 2020 23:36:23

US3012171

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:47:42

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered 'Contact Made (CONTACT MADE)'	Katherine Davis (b) (4)	29 Sep 2020 23:36:23

US3012171

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:47:42

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered empty.	(b) (4) Katherine Davis (b) (4)	29 Sep 2020 23:36:23

US3012171

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:47:42

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered 'Yes (Y)'	Katherine Davis (b) (4)	29 Sep 2020 23:36:29

US3012171

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:47:42

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User entered 'I'	System	29 Sep 2020 23:36:29

US3012171

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:47:42

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered 'Yes (Y)'	(b) (4) Tambra Dora (b) (4)	06 Oct 2020 20:12:04

US3012171

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:47:42

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered '6 Oct 2020'	Tambra Dora (b) (4)	06 Oct 2020 20:12:04

US3012171

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:47:42

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered 'Contact Made (CONTACT MADE)'	Tambra Dora (b) (4)	06 Oct 2020 20:12:04

US3012171

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:47:42

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered empty.	(b) (4) Tambra Dora (b) (4)	06 Oct 2020 20:12:04

US3012171

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:47:42

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered 'Yes (Y)'	(b) (4) Tambra Dora (b) (4)	06 Oct 2020 20:11:55

US3012171

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:47:42

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User entered 'I'	System	06 Oct 2020 20:11:55

US3012171

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:47:42

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:34:05
User entered 'Yes (Y)'	Jennifer Leyva (b) (4)	13 Oct 2020 18:34:56

US3012171

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:47:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:34:05
User entered '13 Oct 2020'	Jennifer Leyva (b) (4)	13 Oct 2020 18:34:56

US3012171

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:47:42

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:34:05
User entered 'Clinic (Clinic)'	Jennifer Leyva (b) (4)	13 Oct 2020 18:34:56

US3012171

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:47:42

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User entered 'VISIT3'	System	13 Oct 2020 18:34:56

US3012171

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:47:42

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:34:05
User entered 'Yes (Y)'	Jennifer Leyva (b) (4)	13 Oct 2020 18:35:16

US3012171

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:47:42

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:34:05
User entered '13 Oct 2020'	Jennifer Leyva (b) (4)	13 Oct 2020 18:35:16

US3012171

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:47:42

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:34:05
User entered '11:24'	Jennifer Leyva (b) (4)	13 Oct 2020 18:35:16

US3012171

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:47:42

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User entered '13 Oct 2020 11:24'	System	13 Oct 2020 18:35:16

US3012171

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:47:42

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:34:05
User entered '99.1' F	Jennifer Leyva (b) (4)	13 Oct 2020 18:35:16

US3012171

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:47:42

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:34:05
User entered 'Oral (Oral)'	Jennifer Leyva (b) (4)	13 Oct 2020 18:35:16

US3012171

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:47:42

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:34:05
User entered empty.	Jennifer Leyva (b) (4)	13 Oct 2020 18:35:16

US3012171

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:47:42

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:34:05
User entered '90'	Jennifer Leyva (b) (4)	13 Oct 2020 18:35:16

US3012171

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:47:42

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User entered 'bpm'	System	13 Oct 2020 18:35:16

US3012171

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:47:42

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:34:05
User entered '14'	Jennifer Leyva (b) (4)	13 Oct 2020 18:35:16

US3012171

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:47:42

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User entered 'breaths/min'	System	13 Oct 2020 18:35:16

US3012171

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:47:42

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:34:05
User entered '119'	Jennifer Leyva (b) (4)	13 Oct 2020 18:35:16

US3012171

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:47:42

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User entered 'mmHg'	System	13 Oct 2020 18:35:16

US3012171

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:47:42

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:34:05
User entered '78'	Jennifer Leyva (b) (4)	13 Oct 2020 18:35:16

US3012171

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:47:42

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User entered 'mmHg'	System	13 Oct 2020 18:35:16

US3012171

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:47:42

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	03 Apr 2021 16:29:24

US3012171

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:47:42

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24

US3012171

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:47:42

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered 'No (N)'	Jennifer Leyva (b) (4)	13 Oct 2020 18:36:12

US3012171

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:47:42

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered empty.	Jennifer Leyva (b) (4)	13 Oct 2020 18:36:12

US3012171

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:47:42

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered 'Yes (Y)'	Jennifer Leyva (b) (4)	13 Oct 2020 18:36:27

US3012171

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:47:42

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered '13 Oct 2020'	Jennifer Leyva (b) (4)	13 Oct 2020 18:36:27

US3012171

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:47:42

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered '11:45'	Jennifer Leyva (b) (4)	13 Oct 2020 18:36:27

US3012171

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:47:42

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User entered '13 Oct 2020 11:45'	System	13 Oct 2020 18:36:27

US3012171

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:47:42

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:33:40
User entered 'Yes (Y)'	Jennifer Leyva (b) (4)	13 Oct 2020 18:36:29

US3012171

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:47:42

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User entered 'I'	System	13 Oct 2020 18:36:29

US3012171

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
Data entry locked.	System	18 Aug 2020 21:19:51
User entered 'Day 64'	System	18 Aug 2020 21:19:51

US3012171

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[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)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-10-18T00:01:22', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '204106e4-1961-4739-88a5-b68791fe8f84'	System	18 Oct 2020 05:01:40
User entered 'No (N)'	System	18 Oct 2020 05:01:40

US3012171

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Have you been exposed to someone with 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)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-10-18T00:01:26', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '204106e4-1961-4739-88a5-b68791fe8f84'	System	18 Oct 2020 05:01:40
User entered 'No (N)'	System	18 Oct 2020 05:01:40

US3012171

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-10-18T00:01:30', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '204106e4-1961-4739-88a5-b68791fe8f84'	System	18 Oct 2020 05:01:40
User entered '18 Oct 2020 00:01:30'	System	18 Oct 2020 05:01:40

US3012171

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
Data entry locked.	System	18 Aug 2020 21:19:51
User entered '18 Oct 2020 00:01'	System	18 Aug 2020 21:19:51

US3012171

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
Data entry locked.	System	18 Aug 2020 21:19:51
User entered '22 Oct 2020 23:59'	System	18 Aug 2020 21:19:51

US3012171

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
Data entry locked.	System	18 Aug 2020 21:19:51
User entered 'Day 71'	System	18 Aug 2020 21:19:51

US3012171

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[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)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-10-27T11:37:13', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '4dd1c07b-1d59-46f2-9ab8-f596bc28bdf'	System	27 Oct 2020 16:37:21
User entered 'No (N)'	System	27 Oct 2020 16:37:21

US3012171

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Have you been exposed to someone with 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)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-10-27T11:37:16', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '4dd1c07b-1d59-46f2-9ab8-f596bc28bdf'	System	27 Oct 2020 16:37:21
User entered 'No (N)'	System	27 Oct 2020 16:37:21

US3012171

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-10-27T11:37:19', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '4dd1c07b-1d59-46f2-9ab8-f596bc28bdf'	System	27 Oct 2020 16:37:21
User entered '27 Oct 2020 11:37:19'	System	27 Oct 2020 16:37:21

US3012171

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
Data entry locked.	System	18 Aug 2020 21:19:51
User entered '25 Oct 2020 00:01'	System	18 Aug 2020 21:19:51

US3012171

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
Data entry locked.	System	18 Aug 2020 21:19:51
User entered '29 Oct 2020 23:59'	System	18 Aug 2020 21:19:51

US3012171

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:01:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:30:53
Data entry locked.	System	18 Aug 2020 21:19:51
User entered 'Day 78'	System	18 Aug 2020 21:19:51

US3012171

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[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)	24 Apr 2021 08:01:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:30:53

US3012171

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

Have you been exposed to someone with 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)	24 Apr 2021 08:01:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:30:53

US3012171

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:01:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:30:53

US3012171

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:01:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:30:53

US3012171

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:01:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:30:53

US3012171

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:01:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:30:53

US3012171

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:01:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:30:53

US3012171

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:01:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:30:53

US3012171

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:01:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:30:53

US3012171

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:01:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:30:53

US3012171

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:01:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:30:53

US3012171

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:01:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:30:53

US3012171

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:01:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:30:53

US3012171

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:01:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:30:53

US3012171

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:01:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:30:53

US3012171

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:01:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:30:53

US3012171

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:01:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:30:53

US3012171

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:01:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:30:53

US3012171

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:01:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:30:53

US3012171

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:01:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:30:53

US3012171

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:01:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:30:53

US3012171

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:01:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:30:53

US3012171

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:01:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:30:53

US3012171

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:01:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:30:53

US3012171

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:01:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:30:53

US3012171

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:01:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:30:53
Data entry locked.	System	18 Aug 2020 21:19:51
User entered '01 Nov 2020 00:01'	System	18 Aug 2020 21:19:51

US3012171

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:01:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:30:53
Data entry locked.	System	18 Aug 2020 21:19:51
User entered '05 Nov 2020 23:59'	System	18 Aug 2020 21:19:51

US3012171

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
Data entry locked.	System	18 Aug 2020 21:19:51
User entered 'Day 92'	System	18 Aug 2020 21:19:51

US3012171

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[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)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-11-16T18:18:57', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '480194f9-7643-4d35-83fb-9413faf35a63'	System	17 Nov 2020 00:19:06
User entered 'No (N)'	System	17 Nov 2020 00:19:06

US3012171

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Have you been exposed to someone with 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)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-11-16T18:19:00', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '480194f9-7643-4d35-83fb-9413faf35a63'	System	17 Nov 2020 00:19:06
User entered 'No (N)'	System	17 Nov 2020 00:19:06

US3012171

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-11-16T18:19:03', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '480194f9-7643-4d35-83fb-9413faf35a63'	System	17 Nov 2020 00:19:06
User entered '16 Nov 2020 18:19:03'	System	17 Nov 2020 00:19:06

US3012171

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
Data entry locked.	System	18 Aug 2020 21:19:51
User entered '15 Nov 2020 00:01'	System	18 Aug 2020 21:19:51

US3012171

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:49
Data entry locked.	System	18 Aug 2020 21:19:51
User entered '19 Nov 2020 23:59'	System	18 Aug 2020 21:19:51

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '19 Nov 2020 00:01'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '23 Nov 2020 23:59'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[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 (471bcacba1c5744e)', Time: '2020-11-26T00:01:42', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: 'f07ae97a-8568-4ee8-8aa3-9d73eec0dfc3'	System	26 Nov 2020 06:02:09
User entered 'No (N)'	System	26 Nov 2020 06:02:09

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Have you been exposed to someone with 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 (471bcacba1c5744e)', Time: '2020-11-26T00:01:49', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: 'f07ae97a-8568-4ee8-8aa3-9d73eec0dfc3'	System	26 Nov 2020 06:02:09
User entered 'No (N)'	System	26 Nov 2020 06:02:09

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-11-26T00:01:54', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: 'f07ae97a-8568-4ee8-8aa3-9d73eec0dfc3'	System	26 Nov 2020 06:02:09
User entered '26 Nov 2020 00:01:54'	System	26 Nov 2020 06:02:09

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '26 Nov 2020 00:01'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '30 Nov 2020 23:59'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[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 (471bcacba1c5744e)', Time: '2020-12-03T05:15:11', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '377da262-3a3e-42ea-9199-fda93aac0c59'	System	03 Dec 2020 11:15:33
User entered 'No (N)'	System	03 Dec 2020 11:15:33

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

Have you been exposed to someone with 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 (471bcacba1c5744e)', Time: '2020-12-03T05:15:27', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '377da262-3a3e-42ea-9199-fda93aac0c59'	System	03 Dec 2020 11:15:33
User entered 'No (N)'	System	03 Dec 2020 11:15:33

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-12-03T05:15:30', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '377da262-3a3e-42ea-9199-fda93aac0c59'	System	03 Dec 2020 11:15:33
User entered '03 Dec 2020 05:15:30'	System	03 Dec 2020 11:15:33

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '03 Dec 2020 00:01'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '07 Dec 2020 23:59'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[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 (471bcacba1c5744e)', Time: '2020-12-10T04:28:52', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: 'e4425009-2bb8-4244-b019-c39e5c06966e'	System	10 Dec 2020 10:29:03
User entered 'No (N)'	System	10 Dec 2020 10:29:03

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

Have you been exposed to someone with 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 (471bcacba1c5744e)', Time: '2020-12-10T04:28:55', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: 'e4425009-2bb8-4244-b019-c39e5c06966e'	System	10 Dec 2020 10:29:03
User entered 'No (N)'	System	10 Dec 2020 10:29:03

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-12-10T04:28:58', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: 'e4425009-2bb8-4244-b019-c39e5c06966e'	System	10 Dec 2020 10:29:03
User entered '10 Dec 2020 04:28:58'	System	10 Dec 2020 10:29:03

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '10 Dec 2020 00:01'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '14 Dec 2020 23:59'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[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 (471bcacba1c5744e)', Time: '2020-12-21T14:30:56', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '67c986c7-a1ed-4439-b3a4-78c4182a303e'	System	21 Dec 2020 20:31:12
User entered 'No (N)'	System	21 Dec 2020 20:31:12

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

Have you been exposed to someone with 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 (471bcacba1c5744e)', Time: '2020-12-21T14:31:05', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '67c986c7-a1ed-4439-b3a4-78c4182a303e'	System	21 Dec 2020 20:31:12
User entered 'No (N)'	System	21 Dec 2020 20:31:12

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2020-12-21T14:31:07', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '67c986c7-a1ed-4439-b3a4-78c4182a303e' User entered '21 Dec 2020 14:31:07'	System	21 Dec 2020 20:31:12
	System	21 Dec 2020 20:31:12

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '17 Dec 2020 00:01'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '21 Dec 2020 23:59'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '24 Dec 2020 00:01'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '28 Dec 2020 23:59'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[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 (471bcacba1c5744e)', Time: '2021-01-01T17:39:08', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: 'f00cc3e0-8ec7-4a7b-9e09-d6b61544c0ea'	System	01 Jan 2021 23:39:16
User entered 'No (N)'	System	01 Jan 2021 23:39:16

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Have you been exposed to someone with 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 (471bcacba1c5744e)', Time: '2021-01-01T17:39:11', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: 'f00cc3e0-8ec7-4a7b-9e09-d6b61544c0ea'	System	01 Jan 2021 23:39:16
User entered 'No (N)'	System	01 Jan 2021 23:39:16

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2021-01-01T17:39:13', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: 'f00cc3e0-8ec7-4a7b-9e09-d6b61544c0ea' User entered '01 Jan 2021 17:39:13'	System	01 Jan 2021 23:39:16

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '31 Dec 2020 00:01'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '04 Jan 2021 23:59'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[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 (471bcacba1c5744e)', Time: '2021-01-07T22:07:41', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: 'f927efc3-7274-4f45-8c16-8270f96f2a74'	System	08 Jan 2021 04:07:50
User entered 'No (N)'	System	08 Jan 2021 04:07:50

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

Have you been exposed to someone with 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 (471bcacba1c5744e)', Time: '2021-01-07T22:07:45', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: 'f927efc3-7274-4f45-8c16-8270f96f2a74'	System	08 Jan 2021 04:07:50
User entered 'No (N)'	System	08 Jan 2021 04:07:50

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2021-01-07T22:07:47', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: 'f927efc3-7274-4f45-8c16-8270f96f2a74'	System	08 Jan 2021 04:07:50
User entered '07 Jan 2021 22:07:47'	System	08 Jan 2021 04:07:50

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '07 Jan 2021 00:01'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '11 Jan 2021 23:59'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[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 (471bcacba1c5744e)', Time: '2021-01-15T05:50:11', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: 'd859fa96-5a4c-4966-bbc9-65107ac7f0de'	System	15 Jan 2021 11:50:30
User entered 'Yes (Y)'	System	15 Jan 2021 11:50:30

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

Have you been exposed to someone with 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 (471bcacba1c5744e)', Time: '2021-01-15T05:50:14', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: 'd859fa96-5a4c-4966-bbc9-65107ac7f0de'	System	15 Jan 2021 11:50:30
User entered 'No (N)'	System	15 Jan 2021 11:50:30

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[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 (471bcacba1c5744e)', Time: '2021-01-15T05:50:19', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: 'd859fa96-5a4c-4966-bbc9-65107ac7f0de'	System	15 Jan 2021 11:50:30
User entered 'No (N)'	System	15 Jan 2021 11:50:30

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[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 (471bcacba1c5744e)', Time: '2021-01-15T05:50:23', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: 'd859fa96-5a4c-4966-bbc9-65107ac7f0de'	System	15 Jan 2021 11:50:30
User entered 'No (N)'	System	15 Jan 2021 11:50:30

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2021-01-15T05:50:27', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: 'd859fa96-5a4c-4966-bbc9-65107ac7f0de'	System	15 Jan 2021 11:50:30
User entered '15 Jan 2021 05:50:27'	System	15 Jan 2021 11:50:30

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '14 Jan 2021 00:01'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '18 Jan 2021 23:59'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[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 (471bcacba1c5744e)', Time: '2021-01-23T02:56:44', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '90d2cdd9-c824-4468-9bee-5fb1658c878c'	System	23 Jan 2021 08:56:52
User entered 'No (N)'	System	23 Jan 2021 08:56:52

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

Have you been exposed to someone with 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 (471bcacba1c5744e)', Time: '2021-01-23T02:56:46', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '90d2cdd9-c824-4468-9bee-5fb1658c878c'	System	23 Jan 2021 08:56:52
User entered 'No (N)'	System	23 Jan 2021 08:56:52

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2021-01-23T02:56:48', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '90d2cdd9-c824-4468-9bee-5fb1658c878c' User entered '23 Jan 2021 02:56:48'	System	23 Jan 2021 08:56:52

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '21 Jan 2021 00:01'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '25 Jan 2021 23:59'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[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 (471bcacba1c5744e)', Time: '2021-01-28T00:01:28', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: 'f26110a3-43b6-42a3-b67f-382f611f6740'	System	28 Jan 2021 06:02:00
User entered 'No (N)'	System	28 Jan 2021 06:02:00

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

Have you been exposed to someone with 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 (471bcacba1c5744e)', Time: '2021-01-28T00:01:31', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: 'f26110a3-43b6-42a3-b67f-382f611f6740'	System	28 Jan 2021 06:02:00
User entered 'No (N)'	System	28 Jan 2021 06:02:00

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2021-01-28T00:01:34', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: 'f26110a3-43b6-42a3-b67f-382f611f6740'	System	28 Jan 2021 06:02:00
User entered '28 Jan 2021 00:01:34'	System	28 Jan 2021 06:02:00

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '28 Jan 2021 00:01'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '01 Feb 2021 23:59'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[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 (471bcacba1c5744e)', Time: '2021-02-06T05:37:50', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: 'b4841c00-577b-48a0-87c9-89eecd5d5fad'	System	06 Feb 2021 11:37:59
User entered 'No (N)'	System	06 Feb 2021 11:37:59

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

Have you been exposed to someone with 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 (471bcacba1c5744e)', Time: '2021-02-06T05:37:53', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: 'b4841c00-577b-48a0-87c9-89eecd5d5fad'	System	06 Feb 2021 11:37:59
User entered 'No (N)'	System	06 Feb 2021 11:37:59

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471bcacba1c5744e)', Time: '2021-02-06T05:37:55', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: 'b4841c00-577b-48a0-87c9-89eecd5d5fad'	System	06 Feb 2021 11:37:59
User entered '06 Feb 2021 05:37:55'	System	06 Feb 2021 11:37:59

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '04 Feb 2021 00:01'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '08 Feb 2021 23:59'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '11 Feb 2021 00:01'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '15 Feb 2021 23:59'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '18 Feb 2021 00:01'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '22 Feb 2021 23:59'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[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 (0914F927-4881-4945-A9D6-D0A0A4B1C958)', Time: '2021-03-01T13:55:55-06:00', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: 'a28d864c-b29f-4ecb-94f1-eb29a48fb847'	System	01 Mar 2021 19:56:14
User entered 'No (N)'	System	01 Mar 2021 19:56:14

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

Have you been exposed to someone with 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 (0914F927-4881-4945-A9D6-D0A0A4B1C958)', Time: '2021-03-01T13:56:03-06:00', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: 'a28d864c-b29f-4ecb-94f1-eb29a48fb847'	System	01 Mar 2021 19:56:14
User entered 'No (N)'	System	01 Mar 2021 19:56:14

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0914F927-4881-4945-A9D6-D0A0A4B1C958)', Time: '2021-03-01T13:56:10-06:00', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: 'a28d864c-b29f-4ecb-94f1-eb29a48fb847'	System	01 Mar 2021 19:56:14
User entered '01 Mar 2021 13:56:10'	System	01 Mar 2021 19:56:14

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '25 Feb 2021 00:01'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '01 Mar 2021 23:59'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[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 (0914F927-4881-4945-A9D6-D0A0A4B1C958)', Time: '2021-03-05T18:04:51-06:00', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '3faf843f-5374-490f-af60-a0fad91f4577'	System	06 Mar 2021 00:09:48
User entered 'No (N)'	System	06 Mar 2021 00:09:48

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

Have you been exposed to someone with 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 (0914F927-4881-4945-A9D6-D0A0A4B1C958)', Time: '2021-03-05T18:04:54-06:00', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '3faf843f-5374-490f-af60-a0fad91f4577'	System	06 Mar 2021 00:09:48
User entered 'No (N)'	System	06 Mar 2021 00:09:48

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0914F927-4881-4945-A9D6-D0A0A4B1C958)', Time: '2021-03-05T18:04:58-06:00', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '3faf843f-5374-490f-af60-a0fad91f4577'	System	06 Mar 2021 00:09:48
User entered '05 Mar 2021 18:04:58'	System	06 Mar 2021 00:09:48

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '04 Mar 2021 00:01'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '08 Mar 2021 23:59'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[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 (0914F927-4881-4945-A9D6-D0A0A4B1C958)', Time: '2021-03-11T13:14:34-06:00', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '60f5afcc-b741-45d5-88df-b78b8f2b140f'	System	11 Mar 2021 19:14:45
User entered 'No (N)'	System	11 Mar 2021 19:14:45

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

Have you been exposed to someone with 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 (0914F927-4881-4945-A9D6-D0A0A4B1C958)', Time: '2021-03-11T13:14:38-06:00', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '60f5afcc-b741-45d5-88df-b78b8f2b140f' User entered 'No (N)'	System	11 Mar 2021 19:14:45
	System	11 Mar 2021 19:14:45

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0914F927-4881-4945-A9D6-D0A0A4B1C958)', Time: '2021-03-11T13:14:42-06:00', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '60f5afcc-b741-45d5-88df-b78b8f2b140f' User entered '11 Mar 2021 13:14:42'	System	11 Mar 2021 19:14:45
	System	11 Mar 2021 19:14:45

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '11 Mar 2021 00:01'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '15 Mar 2021 23:59'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[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 (0914F927-4881-4945-A9D6-D0A0A4B1C958)', Time: '2021-03-19T18:33:29-05:00', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '38d9d033-1228-4b58-801c-21d67520a889'	System	19 Mar 2021 23:34:09
User entered 'Yes (Y)'	System	19 Mar 2021 23:34:09

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

Have you been exposed to someone with 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 (0914F927-4881-4945-A9D6-D0A0A4B1C958)', Time: '2021-03-19T18:33:34-05:00', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '38d9d033-1228-4b58-801c-21d67520a889'	System	19 Mar 2021 23:34:09
User entered 'No (N)'	System	19 Mar 2021 23:34:09

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[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 (0914F927-4881-4945-A9D6-D0A0A4B1C958)', Time: '2021-03-19T18:33:39-05:00', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '38d9d033-1228-4b58-801c-21d67520a889'	System	19 Mar 2021 23:34:09
User entered 'No (N)'	System	19 Mar 2021 23:34:09

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[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 (0914F927-4881-4945-A9D6-D0A0A4B1C958)', Time: '2021-03-19T18:33:46-05:00', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '38d9d033-1228-4b58-801c-21d67520a889'	System	19 Mar 2021 23:34:09
User entered 'Yes (Y)'	System	19 Mar 2021 23:34:09

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Please 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 (0914F927-4881-4945-A9D6-D0A0A4B1C958)', Time: '2021-03-19T18:33:53-05:00', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '38d9d033-1228-4b58-801c-21d67520a889'	System	19 Mar 2021 23:34:09
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	19 Mar 2021 23:34:09

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0914F927-4881-4945-A9D6-D0A0A4B1C958)', Time: '2021-03-19T18:33:58-05:00', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '38d9d033-1228-4b58-801c-21d67520a889'	System	19 Mar 2021 23:34:09
User entered '19 Mar 2021 18:33:58'	System	19 Mar 2021 23:34:09

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '18 Mar 2021 00:01'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '22 Mar 2021 23:59'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[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 (0914F927-4881-4945-A9D6-D0A0A4B1C958)', Time: '2021-03-29T03:49:27-05:00', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '77d6044f-7026-4a9f-a644-99f919c96b6e'	System	29 Mar 2021 08:49:39
User entered 'No (N)'	System	29 Mar 2021 08:49:39

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

Have you been exposed to someone with 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 (0914F927-4881-4945-A9D6-D0A0A4B1C958)', Time: '2021-03-29T03:49:32-05:00', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '77d6044f-7026-4a9f-a644-99f919c96b6e'	System	29 Mar 2021 08:49:39
User entered 'No (N)'	System	29 Mar 2021 08:49:39

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0914F927-4881-4945-A9D6-D0A0A4B1C958)', Time: '2021-03-29T03:49:36-05:00', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '77d6044f-7026-4a9f-a644-99f919c96b6e' User entered '29 Mar 2021 03:49:36'	System	29 Mar 2021 08:49:39
	System	29 Mar 2021 08:49:39

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '25 Mar 2021 00:01'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '29 Mar 2021 23:59'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[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 (0914F927-4881-4945-A9D6-D0A0A4B1C958)', Time: '2021-04-01T17:17:48-05:00', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '0c3c99c3-d134-471d-b634-79944c56abe7'	System	01 Apr 2021 22:18:35
User entered 'No (N)'	System	01 Apr 2021 22:18:35

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

Have you been exposed to someone with 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 (0914F927-4881-4945-A9D6-D0A0A4B1C958)', Time: '2021-04-01T17:17:51-05:00', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '0c3c99c3-d134-471d-b634-79944c56abe7'	System	01 Apr 2021 22:18:35
User entered 'No (N)'	System	01 Apr 2021 22:18:35

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0914F927-4881-4945-A9D6-D0A0A4B1C958)', Time: '2021-04-01T17:17:56-05:00', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '0c3c99c3-d134-471d-b634-79944c56abe7'	System	01 Apr 2021 22:18:35
User entered '01 Apr 2021 17:17:56'	System	01 Apr 2021 22:18:35

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '01 Apr 2021 00:01'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '05 Apr 2021 23:59'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[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 (0914F927-4881-4945-A9D6-D0A0A4B1C958)', Time: '2021-04-08T15:08:05-05:00', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '186fe162-f110-4bf7-8868-dddddbcbf880'	System	08 Apr 2021 20:08:16
User entered 'No (N)'	System	08 Apr 2021 20:08:16

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Have you been exposed to someone with 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 (0914F927-4881-4945-A9D6-D0A0A4B1C958)', Time: '2021-04-08T15:08:08-05:00', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '186fe162-f110-4bf7-8868-dddddbcbf880'	System	08 Apr 2021 20:08:16
User entered 'No (N)'	System	08 Apr 2021 20:08:16

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0914F927-4881-4945-A9D6-D0A0A4B1C958)', Time: '2021-04-08T15:08:11-05:00', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '186fe162-f110-4bf7-8868-dddddbcbf880'	System	08 Apr 2021 20:08:16
User entered '08 Apr 2021 15:08:11'	System	08 Apr 2021 20:08:16

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '08 Apr 2021 00:01'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '12 Apr 2021 23:59'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[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 (0914F927-4881-4945-A9D6-D0A0A4B1C958)', Time: '2021-04-15T00:18:20-05:00', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '394b8d69-4969-4662-a165-acc6cb20a611'	System	15 Apr 2021 05:18:31
User entered 'No (N)'	System	15 Apr 2021 05:18:31

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Have you been exposed to someone with 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 (0914F927-4881-4945-A9D6-D0A0A4B1C958)', Time: '2021-04-15T00:18:22-05:00', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '394b8d69-4969-4662-a165-acc6cb20a611'	System	15 Apr 2021 05:18:31
User entered 'No (N)'	System	15 Apr 2021 05:18:31

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0914F927-4881-4945-A9D6-D0A0A4B1C958)', Time: '2021-04-15T00:18:25-05:00', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '394b8d69-4969-4662-a165-acc6cb20a611'	System	15 Apr 2021 05:18:31
User entered '15 Apr 2021 00:18:25'	System	15 Apr 2021 05:18:31

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '15 Apr 2021 00:01'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '19 Apr 2021 23:59'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[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 (0914F927-4881-4945-A9D6-D0A0A4B1C958)', Time: '2021-04-22T17:22:09-05:00', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '82499a91-c9e1-46d2-b28b-07a042a380ce' User entered 'No (N)'	System	22 Apr 2021 22:22:18
	System	22 Apr 2021 22:22:18

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

Have you been exposed to someone with 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 (0914F927-4881-4945-A9D6-D0A0A4B1C958)', Time: '2021-04-22T17:22:12-05:00', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '82499a91-c9e1-46d2-b28b-07a042a380ce' User entered 'No (N)'	System	22 Apr 2021 22:22:18
	System	22 Apr 2021 22:22:18

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0914F927-4881-4945-A9D6-D0A0A4B1C958)', Time: '2021-04-22T17:22:16-05:00', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '82499a91-c9e1-46d2-b28b-07a042a380ce'	System	22 Apr 2021 22:22:18
User entered '22 Apr 2021 17:22:16'	System	22 Apr 2021 22:22:18

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '22 Apr 2021 00:01'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '26 Apr 2021 23:59'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[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 (0914F927-4881-4945-A9D6-D0A0A4B1C958)', Time: '2021-04-29T12:44:51-05:00', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: 'b56ec4da-748e-4e19-b401-0a5a81682a88' User entered 'No (N)'	System	29 Apr 2021 17:45:12
	System	29 Apr 2021 17:45:12

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Have you been exposed to someone with 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 (0914F927-4881-4945-A9D6-D0A0A4B1C958)', Time: '2021-04-29T12:45:03-05:00', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: 'b56ec4da-748e-4e19-b401-0a5a81682a88'	System	29 Apr 2021 17:45:12
User entered 'No (N)'	System	29 Apr 2021 17:45:12

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0914F927-4881-4945-A9D6-D0A0A4B1C958)', Time: '2021-04-29T12:45:07-05:00', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: 'b56ec4da-748e-4e19-b401-0a5a81682a88'	System	29 Apr 2021 17:45:12
User entered '29 Apr 2021 12:45:07'	System	29 Apr 2021 17:45:12

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '29 Apr 2021 00:01'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '03 May 2021 23:59'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '06 May 2021 00:01'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '10 May 2021 23:59'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '13 May 2021 00:01'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '17 May 2021 23:59'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '20 May 2021 00:01'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '24 May 2021 23:59'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '27 May 2021 00:01'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '31 May 2021 23:59'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '03 Jun 2021 00:01'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '07 Jun 2021 23:59'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '10 Jun 2021 00:01'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '14 Jun 2021 23:59'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '17 Jun 2021 00:01'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '21 Jun 2021 23:59'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '24 Jun 2021 00:01'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '28 Jun 2021 23:59'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '01 Jul 2021 00:01'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '05 Jul 2021 23:59'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '08 Jul 2021 00:01'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '12 Jul 2021 23:59'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '15 Jul 2021 00:01'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '19 Jul 2021 23:59'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '22 Jul 2021 00:01'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '26 Jul 2021 23:59'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '29 Jul 2021 00:01'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '02 Aug 2021 23:59'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '05 Aug 2021 00:01'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '09 Aug 2021 23:59'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '12 Aug 2021 00:01'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '16 Aug 2021 23:59'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '19 Aug 2021 00:01'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '23 Aug 2021 23:59'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '26 Aug 2021 00:01'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '30 Aug 2021 23:59'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '02 Sep 2021 00:01'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '06 Sep 2021 23:59'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '09 Sep 2021 00:01'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '13 Sep 2021 23:59'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '16 Sep 2021 00:01'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '20 Sep 2021 23:59'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '23 Sep 2021 00:01'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '27 Sep 2021 23:59'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '30 Sep 2021 00:01'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '04 Oct 2021 23:59'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '07 Oct 2021 00:01'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '11 Oct 2021 23:59'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '14 Oct 2021 00:01'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '18 Oct 2021 23:59'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '21 Oct 2021 00:01'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '25 Oct 2021 23:59'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '28 Oct 2021 00:01'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '01 Nov 2021 23:59'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '04 Nov 2021 00:01'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '08 Nov 2021 23:59'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '11 Nov 2021 00:01'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '15 Nov 2021 23:59'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '18 Nov 2021 00:01'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '22 Nov 2021 23:59'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '25 Nov 2021 00:01'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '29 Nov 2021 23:59'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '02 Dec 2021 00:01'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '06 Dec 2021 23:59'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '09 Dec 2021 00:01'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '13 Dec 2021 23:59'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '16 Dec 2021 00:01'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '20 Dec 2021 23:59'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '23 Dec 2021 00:01'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '27 Dec 2021 23:59'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '30 Dec 2021 00:01'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '03 Jan 2022 23:59'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '06 Jan 2022 00:01'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '10 Jan 2022 23:59'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '13 Jan 2022 00:01'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '17 Jan 2022 23:59'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '20 Jan 2022 00:01'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '24 Jan 2022 23:59'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '27 Jan 2022 00:01'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '31 Jan 2022 23:59'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '03 Feb 2022 00:01'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '07 Feb 2022 23:59'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '10 Feb 2022 00:01'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '14 Feb 2022 23:59'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '17 Feb 2022 00:01'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '21 Feb 2022 23:59'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '24 Feb 2022 00:01'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '28 Feb 2022 23:59'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '03 Mar 2022 00:01'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '07 Mar 2022 23:59'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '10 Mar 2022 00:01'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '14 Mar 2022 23:59'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '17 Mar 2022 00:01'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '21 Mar 2022 23:59'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '24 Mar 2022 00:01'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '28 Mar 2022 23:59'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '31 Mar 2022 00:01'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '04 Apr 2022 23:59'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '07 Apr 2022 00:01'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '11 Apr 2022 23:59'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '14 Apr 2022 00:01'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '18 Apr 2022 23:59'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '21 Apr 2022 00:01'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '25 Apr 2022 23:59'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '28 Apr 2022 00:01'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '02 May 2022 23:59'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '05 May 2022 00:01'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '09 May 2022 23:59'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '12 May 2022 00:01'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '16 May 2022 23:59'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '19 May 2022 00:01'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '23 May 2022 23:59'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '26 May 2022 00:01'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '30 May 2022 23:59'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '02 Jun 2022 00:01'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '06 Jun 2022 23:59'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '09 Jun 2022 00:01'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '13 Jun 2022 23:59'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '16 Jun 2022 00:01'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '20 Jun 2022 23:59'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '23 Jun 2022 00:01'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '27 Jun 2022 23:59'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '30 Jun 2022 00:01'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '04 Jul 2022 23:59'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '07 Jul 2022 00:01'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '11 Jul 2022 23:59'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '14 Jul 2022 00:01'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '18 Jul 2022 23:59'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '21 Jul 2022 00:01'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '25 Jul 2022 23:59'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '28 Jul 2022 00:01'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '01 Aug 2022 23:59'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '04 Aug 2022 00:01'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '08 Aug 2022 23:59'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '11 Aug 2022 00:01'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '15 Aug 2022 23:59'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '18 Aug 2022 00:01'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '22 Aug 2022 23:59'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '25 Aug 2022 00:01'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '29 Aug 2022 23:59'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '01 Sep 2022 00:01'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '05 Sep 2022 23:59'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '08 Sep 2022 00:01'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '12 Sep 2022 23:59'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '15 Sep 2022 00:01'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '19 Sep 2022 23:59'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '22 Sep 2022 00:01'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '26 Sep 2022 23:59'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '29 Sep 2022 00:01'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '03 Oct 2022 23:59'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '06 Oct 2022 00:01'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '10 Oct 2022 23:59'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '13 Oct 2022 00:01'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '17 Oct 2022 23:59'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '20 Oct 2022 00:01'	System	19 Nov 2020 22:30:53

US3012171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:53
Amendment Manager: User entered '24 Oct 2022 23:59'	System	19 Nov 2020 22:30:53

US3012171

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 14:47:42

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:01:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0914F927-4881-4945-A9D6-D0A0A4B1C958)', Time: '2021-03-01T13:56:18-06:00', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '0cb6d383-7c3f-4c03-a3fd-ffff02ebb30f'	System	01 Mar 2021 19:56:30
User entered 'No (N)'	System	01 Mar 2021 19:56:30

US3012171

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 14:47:42

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:01:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0914F927-4881-4945-A9D6-D0A0A4B1C958)', Time: '2021-03-01T13:56:21-06:00', User OID: 'PatientReportedOutcome (US3012171)', ODM File OID: '0cb6d383-7c3f-4c03-a3fd-ffff02ebb30f' User entered '01 Mar 2021 13:56:21'	System	01 Mar 2021 19:56:30
	System	01 Mar 2021 19:56:30

US3012171

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:47:42

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User signature succeeded.	Laurence Chu (b) (4)	05 Mar 2021 19:29:08
User entered 'Yes (Y)'	(b) (4) Pamela Fidler (b) (4)	10 Nov 2020 23:41:17

US3012171

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:47:42

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User signature succeeded.	Laurence Chu (b) (4)	05 Mar 2021 19:29:08
User entered '10 Nov 2020'	(b) (4) Pamela Fidler (b) (4)	10 Nov 2020 23:41:17

US3012171

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:47:42

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User signature succeeded.	Laurence Chu (b) (4)	05 Mar 2021 19:29:08
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Pamela Fidler (b) (4)	10 Nov 2020 23:41:17

US3012171

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:47:42

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User signature succeeded.	Laurence Chu (b) (4)	05 Mar 2021 19:29:08
User entered empty.	(b) (4) Pamela Fidler (b) (4)	10 Nov 2020 23:41:17

US3012171

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:47:42

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User signature succeeded.	Laurence Chu (b) (4)	05 Mar 2021 19:29:08
User entered 'Yes (Y)'	(b) (4) Pamela Fidler (b) (4)	10 Nov 2020 23:41:21

US3012171

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:47:42

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:29:24
User entered 'I'	System	10 Nov 2020 23:41:21

US3012171

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:47:42

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:11:50
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Yes (Y)'	(b) (4) Pamela Fidler (b) (4)	15 Dec 2020 16:56:11

US3012171

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:47:42

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:11:50
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered '15 Dec 2020'	(b) (4) Pamela Fidler (b) (4)	15 Dec 2020 16:56:11

US3012171

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:47:42

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:11:50
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Pamela Fidler (b) (4)	15 Dec 2020 16:56:11

US3012171

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:47:42

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:11:50
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered empty.	(b) (4) Pamela Fidler (b) (4)	15 Dec 2020 16:56:11

US3012171

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:47:42

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:11:50
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Yes (Y)'	(b) (4) Pamela Fidler (b) (4)	15 Dec 2020 16:56:16

US3012171

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:47:42

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:11:50
User entered 'I'	System	15 Dec 2020 16:56:16

US3012171

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:47:42

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:11:50
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Feb 2021 00:03:37

US3012171

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:47:42

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:11:50
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered '14 Jan 2021'	(b) (4), (b) (6)	23 Feb 2021 00:03:37

US3012171

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:47:42

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:11:50
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	23 Feb 2021 00:03:37

US3012171

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:47:42

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:11:50
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered empty.	(b) (4), (b) (6)	23 Feb 2021 00:03:37

US3012171

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:47:42

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:11:50
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Feb 2021 00:03:40

US3012171

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:47:42

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:11:50
User entered '1'	System	23 Feb 2021 00:03:40

US3012171

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:47:42

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:11:50
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Feb 2021 00:03:58

US3012171

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:47:42

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:11:50
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User closed query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	05 Mar 2021 04:41:31
Query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'Correct as entered' (Site from System).	Jennifer Leyva (b) (4) (b) (4)	05 Mar 2021 00:17:34
User opened query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	23 Feb 2021 00:03:58
User entered '22 Feb 2021'	(b) (4), (b) (6)	23 Feb 2021 00:03:58

US3012171

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:47:42

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:11:50
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	23 Feb 2021 00:03:58

US3012171

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:47:42

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:11:50
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered empty.	(b) (4), (b) (6)	23 Feb 2021 00:03:58

US3012171

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:47:42

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:11:50
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Feb 2021 00:04:37

US3012171

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:47:42

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:11:50
User entered 'I'	System	23 Feb 2021 00:04:37

US3012171

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:47:42

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:05:58
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Yes (Y)'	(b) (4) Pamela Fidler (b) (4)	23 Mar 2021 20:30:58

US3012171

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:47:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:05:58
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered '23 Mar 2021'	(b) (4)	23 Mar 2021 20:30:58
	Pamela Fidler (b) (4)	

US3012171

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:47:42

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:05:58
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Clinic (Clinic)'	(b) (4) Pamela Fidler (b) (4)	23 Mar 2021 20:30:58

US3012171

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:47:42

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:05:58
User entered 'VISIT4'	System	23 Mar 2021 20:30:58

US3012171

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:47:42

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:05:58
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 14:53:57
User entered 'Yes (Y)'	Jennifer Leyva (b) (4)	31 Mar 2021 22:26:54

US3012171

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:47:42

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:05:58
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 14:53:57
User entered '23 Mar 2021'	Jennifer Leyva (b) (4)	31 Mar 2021 22:26:54

US3012171

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:47:42

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:05:58
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 14:53:57
User entered '12:00'	Jennifer Leyva (b) (4)	31 Mar 2021 22:26:54

US3012171

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:47:42

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:05:58
User entered '23 Mar 2021 12:00'	System	31 Mar 2021 22:26:54

US3012171

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:47:42

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:05:58
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 14:53:57
User entered '99.2' F	Jennifer Leyva (b) (4)	31 Mar 2021 22:26:54

US3012171

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:47:42

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:05:58
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 14:53:57
User entered 'Oral (Oral)'	Jennifer Leyva (b) (4)	31 Mar 2021 22:26:54

US3012171

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:47:42

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:05:58
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 14:53:57
User entered empty.	Jennifer Leyva (b) (4)	31 Mar 2021 22:26:54

US3012171

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:47:42

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:05:58
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 14:53:57
User entered '94'	Jennifer Leyva (b) (4)	31 Mar 2021 22:26:54

US3012171

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:47:42

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:05:58
User entered 'bpm'	System	31 Mar 2021 22:26:54

US3012171

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:47:42

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:05:58
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 14:53:57
User entered '16'	Jennifer Leyva (b) (4)	31 Mar 2021 22:26:54

US3012171

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:47:42

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:05:58
User entered 'breaths/min'	System	31 Mar 2021 22:26:54

US3012171

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:47:42

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:05:58
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 14:53:57
User entered '106'	Jennifer Leyva (b) (4)	31 Mar 2021 22:26:54

US3012171

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:47:42

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:05:58
User entered 'mmHg'	System	31 Mar 2021 22:26:54

US3012171

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:47:42

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:05:58
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 14:53:57
User entered '69'	Jennifer Leyva (b) (4)	31 Mar 2021 22:26:54

US3012171

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:47:42

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:05:58
User entered 'mmHg'	System	31 Mar 2021 22:26:54

US3012171

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:47:42

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:05:58

US3012171

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:47:42

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:05:58

US3012171

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:47:42

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:05:58
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Yes (Y)'	(b) (4) Pamela Fidler (b) (4)	23 Mar 2021 20:31:17

US3012171

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:47:42

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:05:58
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered '23 Mar 2021'	(b) (4) Pamela Fidler (b) (4)	23 Mar 2021 20:31:17

US3012171

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:47:42

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:05:58
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Yes (Y)'	(b) (4) Pamela Fidler (b) (4)	23 Mar 2021 20:31:31

US3012171

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:47:42

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:05:58
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered '23 Mar 2021'	(b) (4) Pamela Fidler (b) (4)	23 Mar 2021 20:31:31

US3012171

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:47:42

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:05:58
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered '12:31'	(b) (4) Pamela Fidler (b) (4)	23 Mar 2021 20:31:31

US3012171

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:47:42

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:05:58
User entered '23 Mar 2021 12:31'	System	23 Mar 2021 20:31:31

US3012171

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:47:42

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:05:58
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Yes (Y)'	(b) (4) Pamela Fidler (b) (4)	23 Mar 2021 20:31:34

US3012171

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:47:42

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:05:58
User entered 'I'	System	23 Mar 2021 20:31:34

US3012171

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:47:42

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	15 Apr 2021 16:35:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:05:42

US3012171

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:47:42

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	15 Apr 2021 16:35:55
User entered '12 Apr 2021'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:05:42

US3012171

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:47:42

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	15 Apr 2021 16:35:55
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:05:42

US3012171

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:47:42

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	15 Apr 2021 16:35:55
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 18:05:42

US3012171

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:47:42

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	15 Apr 2021 16:35:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:05:46

US3012171

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:47:42

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	12 Apr 2021 18:05:46

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 14:47:42

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:01
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User closed query 'Per GCL Lab Reconciliation: SARS-CoV-2: RQ: As per the query response SWAB data entered. However, as per the above stated query SARS-CoV-2 Sample dated 15 JAN 2021 is reported under illness Visit Day 1 in PPD Central lab and same SARS-CoV-2 serum sample data is missing in EDC. Please review if the SARS-CoV-2 serum sample has been collected then update the details under appropriate visit. Else clarify, thank you' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Mar 2021 17:32:16
Query 'Per GCL Lab Reconciliation: SARS-CoV-2: RQ: As per the query response SWAB data entered. However, as per the above stated query SARS-CoV-2 Sample dated 15 JAN 2021 is reported under illness Visit Day 1 in PPD Central lab and same SARS-CoV-2 serum sample data is missing in EDC. Please review if the SARS-CoV-2 serum sample has been collected then update the details under appropriate visit. Else clarify, thank you' answered with 'updated' (Site from DM).	Pamela Fidler (b) (4)	09 Mar 2021 18:54:01
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2: RQ: As per the query response SWAB data entered. However, as per the above stated query SARS-CoV-2 Sample dated 15 JAN 2021 is reported under illness Visit Day 1 in PPD Central lab and same SARS-CoV-2 serum sample data is missing in EDC. Please review if the SARS-CoV-2 serum sample has been collected then update the details under appropriate visit. Else clarify, thank you' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 07:09:14

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Folder: Covid-19 Assessment 14 Jan 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 14:47:42

[Date of Contact](#)

Audit	User	Time (GMT)
Query ' Per GCL Lab Reconciliation: SARS-CoV-2: RQ: As per the query response SWAB data entered. However, as per the above stated query SARS-CoV-2 Sample dated 15 JAN 2021 is reported under illness Visit Day 1 in PPD Central lab, however the same SARS-CoV-2 serum sample data is missing in EDC. Please review if the SARS-CoV-2 serum sample has been collected then update the details under appropriate visit. Else clarify, thank you ' canceled (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 07:06:12
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2: RQ: As per the query response SWAB data entered. However, as per the above stated query SARS-CoV-2 Sample dated 15 JAN 2021 is reported under illness Visit Day 1 in PPD Central lab, however the same SARS-CoV-2 serum sample data is missing in EDC. Please review if the SARS-CoV-2 serum sample has been collected then update the details under appropriate visit. Else clarify, thank you' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 07:05:13
User closed query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 15 JAN 2021 is reported under illness Visit Day 1 in PPD Central lab, however the same SARS-CoV-2 serum sample data is missing in EDC. Please review if the SARS-CoV-2 serum sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 07:05:13
Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 15 JAN 2021 is reported under illness Visit Day 1 in PPD Central lab, however the same SARS-CoV-2 serum sample data is missing in EDC. Please review if the SARS-CoV-2 serum sample has been collected then update the details under appropriate visit. Else clarify, thank you.' answered with 'Swab data entered' (Site from DM).	Jennifer Leyva (b) (4)	04 Mar 2021 15:36:25

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Folder: Covid-19 Assessment 14 Jan 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 14:47:42

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:01
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered '17:45'	(b) (4), (b) (6)	20 Jan 2021 00:05:26

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Folder: Covid-19 Assessment 14 Jan 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 14:47:42

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:01
User entered '14 Jan 2021 17:45'	System	20 Jan 2021 00:05:26

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Folder: Covid-19 Assessment 14 Jan 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 14:47:42

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:01
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Safety Call (Safety Call)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:05:26

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 14:47:42

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:01
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Jan 2021 00:05:26

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:47:42

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Day 1 (Day 1)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:09:32

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:47:42

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered '31 Dec 2020'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:09:32

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:47:42

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered '0'	(b) (4), (b) (6)	20 Jan 2021 00:09:32

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:47:42

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:09:32

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:47:42

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User entered empty.	System	20 Jan 2021 00:09:32

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:47:42

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:09:32

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:47:42

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:09:32

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:47:42

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:09:32

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:47:42

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:09:32

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:47:42

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:09:32

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:47:42

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	20 Jan 2021 00:09:32

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:47:42

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	20 Jan 2021 00:09:32

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:47:42

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	20 Jan 2021 00:09:32

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:47:42

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:09:32

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:47:42

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:09:32

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:47:42

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4), (b) (6)	20 Jan 2021 00:09:32

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:47:42

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	20 Jan 2021 00:09:32

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:47:42

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	20 Jan 2021 00:09:32

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:47:42

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:09:32

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:47:42

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:09:32

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:47:42

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:09:32

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:47:42

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:09:32

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (2)

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Day 2 (Day 2)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:10:40

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:47:42

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered '1 Jan 2021'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:10:40

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:47:42

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered '0'	(b) (4), (b) (6)	20 Jan 2021 00:10:40

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:47:42

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:10:40

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:47:42

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User entered empty.	System	20 Jan 2021 00:10:40

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:47:42

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:10:40

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:47:42

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:10:40

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:47:42

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:10:40

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:47:42

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:10:40

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:47:42

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Mild (Mild)'	(b) (4), (b) (6)	20 Jan 2021 00:10:40

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:47:42

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	20 Jan 2021 00:10:40

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:47:42

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Moderate (Moderate)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:10:40

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:47:42

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	20 Jan 2021 00:10:40

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:47:42

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:10:40

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:47:42

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:10:40

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:47:42

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:10:40

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:47:42

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	20 Jan 2021 00:10:40

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:47:42

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	20 Jan 2021 00:10:40

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:47:42

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:10:40

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:47:42

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:10:40

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:47:42

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:10:40

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:47:42

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:10:40

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (3)

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Day 3 (Day 3)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:12:11

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:47:42

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered '2 Jan 2021'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:12:11

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:47:42

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered '0'	(b) (4), (b) (6)	20 Jan 2021 00:12:11

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:47:42

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:12:11

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:47:42

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User entered empty.	System	20 Jan 2021 00:12:11

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:47:42

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:12:11

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:47:42

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:12:11

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:47:42

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:12:11

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:47:42

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:12:11

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:47:42

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:12:11

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:47:42

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	20 Jan 2021 00:12:11

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:47:42

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Moderate (Moderate)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:12:11

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:47:42

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	20 Jan 2021 00:12:11

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:47:42

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:12:11

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:47:42

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:12:11

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:47:42

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:12:11

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:47:42

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	20 Jan 2021 00:12:11

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:47:42

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Moderate (Moderate)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:12:11

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (3)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:12:11

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (3)

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:12:11

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:47:42

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:12:11

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:47:42

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:12:11

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:47:42

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Day 4 (Day 4)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:13:07

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:47:42

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered '3 Jan 2021'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:13:07

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:47:42

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered '0'	(b) (4), (b) (6)	20 Jan 2021 00:13:07

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:47:42

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:13:07

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:47:42

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User entered empty.	System	20 Jan 2021 00:13:07

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:47:42

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:13:07

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:47:42

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:13:07

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:47:42

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:13:07

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:47:42

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Mild (Mild)'	(b) (4), (b) (6)	20 Jan 2021 00:13:07

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:47:42

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:13:07

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:47:42

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	20 Jan 2021 00:13:07

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:47:42

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Moderate (Moderate)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:13:07

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:47:42

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	20 Jan 2021 00:13:07

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:47:42

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:13:07

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:47:42

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:13:07

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:47:42

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:13:07

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:47:42

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Moderate (Moderate)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:13:07

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:47:42

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Moderate (Moderate)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:13:07

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:47:42

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:13:07

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:47:42

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:13:07

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:47:42

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:13:07

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:47:42

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:13:07

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:47:42

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Day 5 (Day 5)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:14:14

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:47:42

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered '4 Jan 2021'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:14:14

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:47:42

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered '0'	(b) (4), (b) (6)	20 Jan 2021 00:14:14

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:47:42

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:14:14

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:47:42

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User entered empty.	System	20 Jan 2021 00:14:14

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:47:42

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:14:14

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:47:42

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:14:14

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:47:42

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:14:14

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:47:42

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Mild (Mild)'	(b) (4), (b) (6)	20 Jan 2021 00:14:14

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:47:42

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Mild (Mild)'	(b) (4), (b) (6)	20 Jan 2021 00:14:14

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:47:42

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	20 Jan 2021 00:14:14

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:47:42

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	20 Jan 2021 00:14:14

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:47:42

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Moderate (Moderate)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:14:14

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:47:42

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:14:14

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:47:42

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:14:14

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:47:42

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:14:14

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:47:42

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	20 Jan 2021 00:14:14

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:47:42

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	20 Jan 2021 00:14:14

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:47:42

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:14:14

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:47:42

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:14:14

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:47:42

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:14:14

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:47:42

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:14:14

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:47:42

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Day 6 (Day 6)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:15:18

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:47:42

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered '5 Jan 2021'	(b) (4), (b) (6)	20 Jan 2021 00:15:18

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:47:42

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered '0'	(b) (4), (b) (6)	20 Jan 2021 00:15:18

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:47:42

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:15:18

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:47:42

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User entered empty.	System	20 Jan 2021 00:15:18

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:47:42

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:15:18

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:47:42

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:15:18

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:47:42

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:15:18

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:47:42

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:15:18

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:47:42

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Mild (Mild)'	(b) (4), (b) (6)	20 Jan 2021 00:15:18

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:47:42

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Moderate (Moderate)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:15:18

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:47:42

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Moderate (Moderate)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:15:18

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:47:42

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	20 Jan 2021 00:15:18

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:47:42

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:15:18

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:47:42

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:15:18

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:47:42

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:15:18

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:47:42

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	20 Jan 2021 00:15:18

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:47:42

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	20 Jan 2021 00:15:18

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Folder: Covid-19 Assessment 14 Jan 2021

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:15:18

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (6)

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:15:18

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:47:42

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:15:18

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:47:42

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:15:18

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:47:42

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Day 7 (Day 7)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:16:36

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:47:42

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered '6 Jan 2021'	(b) (4), (b) (6)	20 Jan 2021 00:16:36

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:47:42

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered '0'	(b) (4), (b) (6)	20 Jan 2021 00:16:36

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:47:42

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:16:36

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:47:42

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User entered empty.	System	20 Jan 2021 00:16:36

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:47:42

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:16:36

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:47:42

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:16:36

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:47:42

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Mild (Mild)'	(b) (4), (b) (6)	20 Jan 2021 00:16:36

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:47:42

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:16:36

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:47:42

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Mild (Mild)'	(b) (4), (b) (6)	20 Jan 2021 00:16:36

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:47:42

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	20 Jan 2021 00:16:36

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:47:42

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Moderate (Moderate)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:16:36

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:47:42

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	20 Jan 2021 00:16:36

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:47:42

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:16:36

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:47:42

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4), (b) (6)	20 Jan 2021 00:16:36

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:47:42

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:16:36

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:47:42

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	20 Jan 2021 00:16:36

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:47:42

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	20 Jan 2021 00:16:36

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:47:42

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:16:36

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:47:42

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:16:36

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:47:42

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:16:36

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:47:42

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:16:36

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (8)

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Day 8 (Day 8)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:17:33

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:47:42

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered '7 Jan 2021'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:17:33

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:47:42

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered '0'	(b) (4), (b) (6)	20 Jan 2021 00:17:33

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:47:42

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:17:33

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:47:42

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User entered empty.	System	20 Jan 2021 00:17:33

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:47:42

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:17:33

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:47:42

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:17:33

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:47:42

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Mild (Mild)'	(b) (4), (b) (6)	20 Jan 2021 00:17:33

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:47:42

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Mild (Mild)'	(b) (4), (b) (6)	20 Jan 2021 00:17:33

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:47:42

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Mild (Mild)'	(b) (4), (b) (6)	20 Jan 2021 00:17:33

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:47:42

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	20 Jan 2021 00:17:33

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:47:42

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Moderate (Moderate)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:17:33

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:47:42

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	20 Jan 2021 00:17:33

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:47:42

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:17:33

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:47:42

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4), (b) (6)	20 Jan 2021 00:17:33

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:47:42

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:17:33

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:47:42

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	20 Jan 2021 00:17:33

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:47:42

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	20 Jan 2021 00:17:33

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:47:42

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:17:33

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:47:42

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:17:33

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:47:42

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:17:33

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:47:42

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:17:33

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:47:42

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Day 9 (Day 9)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:18:44

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:47:42

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered '8 Jan 2021'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:18:44

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:47:42

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered '0'	(b) (4), (b) (6)	20 Jan 2021 00:18:44

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:47:42

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:18:44

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:47:42

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User entered empty.	System	20 Jan 2021 00:18:44

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:47:42

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered empty.	(b) (4), (b) (6)	20 Jan 2021 00:18:44

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:47:42

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:18:44

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:47:42

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:18:44

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:47:42

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Mild (Mild)'	(b) (4), (b) (6)	20 Jan 2021 00:18:44

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:47:42

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Mild (Mild)'	(b) (4), (b) (6)	20 Jan 2021 00:18:44

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:47:42

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	20 Jan 2021 00:18:44

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:47:42

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Moderate (Moderate)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:18:44

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:47:42

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Moderate (Moderate)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:18:44

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:47:42

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:18:44

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:47:42

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:18:44

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:47:42

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:18:44

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:47:42

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	20 Jan 2021 00:18:44

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:47:42

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	20 Jan 2021 00:18:44

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:47:42

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:18:44

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:47:42

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:18:44

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:47:42

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:18:44

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:47:42

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:18:44

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:47:42

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Day 10 (Day 10)'	(b) (4), (b) (6)	20 Jan 2021 00:19:49

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:47:42

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered '9 Jan 2021'	(b) (4), (b) (6)	20 Jan 2021 00:19:49

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:47:42

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered '0'	(b) (4), (b) (6)	20 Jan 2021 00:19:49

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:47:42

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered empty.	(b) (4), (b) (6)	20 Jan 2021 00:19:49

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:47:42

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User entered empty.	System	20 Jan 2021 00:19:49

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:47:42

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:19:49

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:47:42

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:19:49

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:47:42

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Mild (Mild)'	(b) (4), (b) (6)	20 Jan 2021 00:19:49

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:47:42

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Mild (Mild)'	(b) (4), (b) (6)	20 Jan 2021 00:19:49

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:47:42

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Mild (Mild)'	(b) (4), (b) (6)	20 Jan 2021 00:19:49

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:47:42

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	20 Jan 2021 00:19:49

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:47:42

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	20 Jan 2021 00:19:49

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:47:42

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	20 Jan 2021 00:19:49

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:47:42

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:19:49

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:47:42

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:19:49

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:47:42

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:19:49

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:47:42

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	20 Jan 2021 00:19:49

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:47:42

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	20 Jan 2021 00:19:49

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:47:42

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4), (b) (6)	20 Jan 2021 00:19:49

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:47:42

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:19:49

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:47:42

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4), (b) (6)	20 Jan 2021 00:19:49

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:47:42

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:19:49

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:47:42

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Day 11 (Day 11)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:20:50

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:47:42

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered '10 Jan 2021'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:20:50

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:47:42

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered '0'	(b) (4), (b) (6)	20 Jan 2021 00:20:50

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:47:42

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered empty.	(b) (4), (b) (6)	20 Jan 2021 00:20:50

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:47:42

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User entered empty.	System	20 Jan 2021 00:20:50

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:47:42

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:20:50

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:47:42

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:20:50

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:47:42

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:20:50

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:47:42

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Mild (Mild)'	(b) (4), (b) (6)	20 Jan 2021 00:20:50

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:47:42

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Mild (Mild)'	(b) (4), (b) (6)	20 Jan 2021 00:20:50

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:47:42

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	20 Jan 2021 00:20:50

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:47:42

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Moderate (Moderate)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:20:50

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:47:42

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	20 Jan 2021 00:20:50

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:47:42

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:20:50

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:47:42

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:20:50

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:47:42

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:20:50

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:47:42

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	20 Jan 2021 00:20:50

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:47:42

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	20 Jan 2021 00:20:50

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (11)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:20:50

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (11)

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:20:50

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:47:42

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:20:50

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:47:42

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:20:50

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Day 12 (Day 12)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:21:47

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Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:47:42

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered '11 Jan 2021'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:21:47

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:47:42

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered '0'	(b) (4), (b) (6)	20 Jan 2021 00:21:47

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Generated On: 09 Jun 2021 14:47:42

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:21:47

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:47:42

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User entered empty.	System	20 Jan 2021 00:21:47

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:47:42

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:21:47

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:47:42

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:21:47

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:47:42

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:21:47

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:47:42

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:21:47

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:47:42

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Mild (Mild)'	(b) (4), (b) (6)	20 Jan 2021 00:21:47

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:47:42

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	20 Jan 2021 00:21:47

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:47:42

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Moderate (Moderate)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:21:47

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:47:42

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Moderate (Moderate)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:21:47

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:47:42

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:21:47

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:47:42

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:21:47

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:47:42

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:21:47

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:47:42

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Moderate (Moderate)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:21:47

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:47:42

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	20 Jan 2021 00:21:47

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:47:42

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:21:47

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:47:42

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:21:47

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:47:42

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:21:47

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (12)

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[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:21:47

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (13)

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Day 13 (Day 13)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:22:47

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 14:47:42

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered '12 Jan 2021'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:22:47

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Form: Symptom Log (13)

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered '0'	(b) (4), (b) (6)	20 Jan 2021 00:22:47

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 14:47:42

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:22:47

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 14:47:42

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User entered empty.	System	20 Jan 2021 00:22:47

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[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:22:47

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 14:47:42

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:22:47

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 14:47:42

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:22:47

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 14:47:42

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Mild (Mild)'	(b) (4), (b) (6)	20 Jan 2021 00:22:47

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 14:47:42

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	20 Jan 2021 00:22:47

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 14:47:42

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	20 Jan 2021 00:22:47

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 14:47:42

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	20 Jan 2021 00:22:47

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 14:47:42

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	20 Jan 2021 00:22:47

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 14:47:42

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:22:47

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 14:47:42

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:22:47

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 14:47:42

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4), (b) (6)	20 Jan 2021 00:22:47

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Folder: Covid-19 Assessment 14 Jan 2021

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Generated On: 09 Jun 2021 14:47:42

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	20 Jan 2021 00:22:47

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 14:47:42

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	20 Jan 2021 00:22:47

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (13)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:22:47

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (13)

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:22:47

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 14:47:42

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:22:47

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

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[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:22:47

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Day 14 (Day 14)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:23:39

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Folder: Covid-19 Assessment 14 Jan 2021

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[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered '13 Jan 2021'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:23:39

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:47:42

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered '0'	(b) (4), (b) (6)	20 Jan 2021 00:23:39

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Folder: Covid-19 Assessment 14 Jan 2021

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[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:23:39

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (14)

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[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User entered empty.	System	20 Jan 2021 00:23:39

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[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:23:39

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[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:23:39

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Folder: Covid-19 Assessment 14 Jan 2021

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[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:23:39

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (14)

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[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:23:39

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Folder: Covid-19 Assessment 14 Jan 2021

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[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Moderate (Moderate)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:23:39

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:47:42

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	20 Jan 2021 00:23:39

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:47:42

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Moderate (Moderate)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:23:39

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:47:42

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	20 Jan 2021 00:23:39

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:47:42

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4), (b) (6)	20 Jan 2021 00:23:39

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:47:42

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:23:39

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:47:42

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:23:39

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:47:42

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	20 Jan 2021 00:23:39

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:47:42

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	20 Jan 2021 00:23:39

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:47:42

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:23:39

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:47:42

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:23:39

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:47:42

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:23:39

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:47:42

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:23:39

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 14:47:42

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Day 15 (Day 15)'	(b) (4), (b) (6)	20 Jan 2021 00:24:35

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 14:47:42

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered '14 Jan 2021'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:24:35

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 14:47:42

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered '0'	(b) (4), (b) (6)	20 Jan 2021 00:24:35

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 14:47:42

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:24:35

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 14:47:42

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User entered empty.	System	20 Jan 2021 00:24:35

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 14:47:42

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:24:35

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 14:47:42

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Mild (Mild)'	(b) (4), (b) (6)	20 Jan 2021 00:24:35

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 14:47:42

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:24:35

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 14:47:42

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Mild (Mild)'	(b) (4), (b) (6)	20 Jan 2021 00:24:35

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 14:47:42

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	20 Jan 2021 00:24:35

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 14:47:42

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	20 Jan 2021 00:24:35

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 14:47:42

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Moderate (Moderate)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:24:35

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 14:47:42

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	20 Jan 2021 00:24:35

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 14:47:42

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:24:35

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 14:47:42

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4), (b) (6)	20 Jan 2021 00:24:35

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 14:47:42

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:24:35

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 14:47:42

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	20 Jan 2021 00:24:35

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 14:47:42

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	20 Jan 2021 00:24:35

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 14:47:42

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4), (b) (6)	20 Jan 2021 00:24:35

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 14:47:42

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:24:35

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 14:47:42

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4), (b) (6)	20 Jan 2021 00:24:35

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 14:47:42

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4), (b) (6)	20 Jan 2021 00:24:35

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:47:42

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Day 16 (Day 16)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:26:24

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:47:42

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered '15 Jan 2021'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:26:24

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:47:42

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered '0'	(b) (4), (b) (6)	20 Jan 2021 00:26:24

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:47:42

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered empty.	(b) (4), (b) (6)	20 Jan 2021 00:26:24

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:47:42

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User entered empty.	System	20 Jan 2021 00:26:24

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:47:42

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered empty.	(b) (4), (b) (6)	20 Jan 2021 00:26:24

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:47:42

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:26:24

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:47:42

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:26:24

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:47:42

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:26:24

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:47:42

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:26:24

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:47:42

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Mild (Mild)'	(b) (4), (b) (6)	20 Jan 2021 00:26:24

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:47:42

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:26:24

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:47:42

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:26:24

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:47:42

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:26:24

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:47:42

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:26:24

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:47:42

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:26:24

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:47:42

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Mild (Mild)'	(b) (4), (b) (6)	20 Jan 2021 00:26:24

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:47:42

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:26:24

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:47:42

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:26:24

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:47:42

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:26:24

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:47:42

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:26:24

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:47:42

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4), (b) (6)	20 Jan 2021 00:26:24

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Day 17 (Day 17)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:28:05

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Form: Symptom Log (17)

Generated On: 09 Jun 2021 14:47:42

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered '16 Jan 2021'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:28:05

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 14:47:42

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered '0'	(b) (4), (b) (6)	20 Jan 2021 00:28:05

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 14:47:42

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered '97'	(b) (4), (b) (6)	20 Jan 2021 00:28:05

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 14:47:42

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User entered '%'	System	20 Jan 2021 00:28:05

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (17)

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[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered '98.1' F	(b) (4), (b) (6)	20 Jan 2021 00:28:05

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 14:47:42

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:28:05

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 14:47:42

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Mild (Mild)'	(b) (4), (b) (6)	20 Jan 2021 00:28:05

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 14:47:42

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:28:05

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 14:47:42

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:28:05

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 14:47:42

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:28:05

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 14:47:42

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:28:05

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 14:47:42

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:28:05

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 14:47:42

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:28:05

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 14:47:42

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:28:05

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 14:47:42

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4), (b) (6)	20 Jan 2021 00:28:05

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 14:47:42

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:28:05

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 14:47:42

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Mild (Mild)'	(b) (4), (b) (6)	20 Jan 2021 00:28:05

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 14:47:42

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:28:05

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 14:47:42

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:28:05

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 14:47:42

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:28:05

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (17)

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[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:28:05

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Folder: Covid-19 Assessment 14 Jan 2021

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Day 18 (Day 18)'	(b) (4), (b) (6)	20 Jan 2021 00:30:13

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Folder: Covid-19 Assessment 14 Jan 2021

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Generated On: 09 Jun 2021 14:47:42

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered '17 Jan 2021'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:30:13

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (18)

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered '0'	(b) (4), (b) (6)	20 Jan 2021 00:30:13

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 14:47:42

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered '99'	(b) (4), (b) (6)	20 Jan 2021 00:30:13

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (18)

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[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User entered '%'	System	20 Jan 2021 00:30:13

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[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered '97.9' F	(b) (4), (b) (6)	20 Jan 2021 00:30:13

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 14:47:42

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:30:13

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 14:47:42

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:30:13

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 14:47:42

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:30:13

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 14:47:42

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:30:13

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 14:47:42

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:30:13

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 14:47:42

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:30:13

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 14:47:42

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:30:13

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (18)

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[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:30:13

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 14:47:42

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:30:13

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (18)

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[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4), (b) (6)	20 Jan 2021 00:30:13

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 14:47:42

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Mild (Mild)'	(b) (4), (b) (6)	20 Jan 2021 00:30:13

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 14:47:42

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:30:13

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (18)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:30:13

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (18)

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4), (b) (6)	20 Jan 2021 00:30:13

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Folder: Covid-19 Assessment 14 Jan 2021

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[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:30:13

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (18)

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[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:30:13

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Day 19 (Day 19)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:32:57

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 14:47:42

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered '18 Jan 2021'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:32:57

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 14:47:42

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered '0'	(b) (4), (b) (6)	20 Jan 2021 00:32:57

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (19)

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[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered '98'	(b) (4), (b) (6)	20 Jan 2021 00:32:57

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 14:47:42

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User entered '%'	System	20 Jan 2021 00:32:57

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[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered '97.7' F	(b) (4), (b) (6)	20 Jan 2021 00:32:57

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[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:32:57

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (19)

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[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:32:57

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (19)

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[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:32:57

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Folder: Covid-19 Assessment 14 Jan 2021

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[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:32:57

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Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 14:47:42

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:32:57

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 14:47:42

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:32:57

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 14:47:42

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4), (b) (6)	20 Jan 2021 00:32:57

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 14:47:42

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:32:57

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 14:47:42

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:32:57

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 14:47:42

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:32:57

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 14:47:42

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:32:57

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 14:47:42

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Mild (Mild)'	(b) (4), (b) (6)	20 Jan 2021 00:32:57

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 14:47:42

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4), (b) (6)	20 Jan 2021 00:32:57

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 14:47:42

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:32:57

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 14:47:42

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:32:57

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 14:47:42

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:32:57

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 14:47:42

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 14:47:42

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 14:47:42

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 14:47:42

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 14:47:42

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 14:47:42

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 14:47:42

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 14:47:42

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 14:47:42

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 14:47:42

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 14:47:42

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 14:47:42

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 14:47:42

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 14:47:42

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 14:47:42

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 14:47:42

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 14:47:42

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 14:47:42

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 14:47:42

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 14:47:42

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 14:47:42

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 14:47:42

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:09

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 14:47:42

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:18
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered '15 Jan 2021'	Jennifer Leyva (b) (4)	27 Jan 2021 17:34:39

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 14:47:42

[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 20:09:18
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Yes (Y)'	Jennifer Leyva (b) (4)	27 Jan 2021 17:34:39

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 14:47:42

[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 20:09:18
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'No (N)'	Jennifer Leyva (b) (4)	27 Jan 2021 17:34:39

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 14:47:42

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:18
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User closed query 'Per CDM: A diagnostic test has been completed, however, the associated Illness visit has not been added to the database. Please agree to add a COVID-19 Illness Visit via Add Events and complete all Illness visit forms, or else clarify' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Mar 2021 05:20:48
Query 'Per CDM: A diagnostic test has been completed, however, the associated Illness visit has not been added to the database. Please agree to add a COVID-19 Illness Visit via Add Events and complete all Illness visit forms, or else clarify' answered with 'updated' (Site from DM).	Pamela Fidler (b) (4)	09 Mar 2021 18:53:47
User opened query 'Per CDM: A diagnostic test has been completed, however, the associated Illness visit has not been added to the database. Please agree to add a COVID-19 Illness Visit via Add Events and complete all Illness visit forms, or else clarify' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 15:30:50
User entered '15 Jan 2021'	Jennifer Leyva (b) (4) (b) (4)	27 Jan 2021 17:34:39

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 14:47:42

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:18
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Jennifer Leyva (b) (4)	27 Jan 2021 17:34:39

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 14:47:42

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:18
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered empty.	Jennifer Leyva (b) (4)	27 Jan 2021 17:34:39

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 14:47:42

[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 20:09:18
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'No (N)'	Jennifer Leyva (b) (4)	27 Jan 2021 17:34:39

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 14:47:42

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:18
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered empty.	Jennifer Leyva (b) (4)	27 Jan 2021 17:34:39

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 14:47:42

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:18
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered empty.	Jennifer Leyva (b) (4)	27 Jan 2021 17:34:39

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 14:47:42

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:18
User entered '0'	System	27 Jan 2021 17:34:39

US3012171

Folder: Covid-19 Assessment 14 Jan 2021

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 14:47:42

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:09:24
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 01:18:49
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 01:18:34
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:05:32

US3012171

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 14:47:42

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:27
User accepted default value 'Day 3 (Day 3)'	Pamela Fidler (b) (4)	09 Mar 2021 18:52:36

US3012171

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 14:47:42

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:27
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Yes (Y)'	(b) (4)	09 Mar 2021 18:52:36
	Pamela Fidler (b) (4)	

US3012171

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 14:47:42

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:27
User closed query 'Per GCL LAB reconciliation: Saliva: Sample dated 17JAN2021 is missing in PPD. Please provide the Accession # and Tracking number with the shipping date to track the sample in PPD. Thank you.' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 08:16:23
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
Query 'Per GCL LAB reconciliation: Saliva: Sample dated 17JAN2021 is missing in PPD. Please provide the Accession # and Tracking number with the shipping date to track the sample in PPD. Thank you.'	(b) (4)	
answered with '1f636663312 9417 0334 3140 02/01/2021' (Site from DM).	Pamela Fidler (b) (4)	24 Mar 2021 20:41:47
User opened query 'Per GCL LAB reconciliation: Saliva: Sample dated 17JAN2021 is missing in PPD. Please provide the Accession # and Tracking number with the shipping date to track the sample in PPD. Thank you.' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 07:23:16
User entered '17 Jan 2021'	Pamela Fidler (b) (4)	09 Mar 2021 18:52:36

US3012171

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 14:47:42

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:27
User accepted default value 'Day 5 (Day 5)'	Pamela Fidler (b) (4)	09 Mar 2021 18:52:36

US3012171

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 14:47:42

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:27
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 14:53:57
Signature has been broken.	(b) (4) Pamela Fidler (b) (4)	30 Mar 2021 15:44:08
User entered 'No (N)' reason for change: Data Entry Error	Pamela Fidler (b) (4)	30 Mar 2021 15:44:08
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Yes (Y)'	(b) (4) Pamela Fidler (b) (4)	09 Mar 2021 18:52:36

US3012171

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 14:47:42

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:27
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 14:53:57
User closed query ' Per GCL LAB reconciliation: Saliva: Re-query: Sample dated 19JAN2021 is still missing in PPD. Please provide the Accession # and Tracking number with the shipping date to track the sample in PPD. Thank you.' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 13:02:25
Query ' Per GCL LAB reconciliation: Saliva: Re-query: Sample dated 19JAN2021 is still missing in PPD. Please provide the Accession # and Tracking number with the shipping date to track the sample in PPD. Thank you.' answered with 'Updated' (Site from DM).	Pamela Fidler (b) (4)	30 Mar 2021 15:44:21
Signature has been broken.	Pamela Fidler (b) (4)	30 Mar 2021 15:44:08
User entered empty; reason for change Data Entry Error	Pamela Fidler (b) (4)	30 Mar 2021 15:44:08
User opened query ' Per GCL LAB reconciliation: Saliva: Re-query: Sample dated 19JAN2021 is still missing in PPD. Please provide the Accession # and Tracking number with the shipping date to track the sample in PPD. Thank you.' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 05:24:27
User closed query 'Per GCL LAB reconciliation: Saliva: Sample dated 19JAN2021 is missing in PPD. Please provide the Accession # and Tracking number with the shipping date to track the sample in PPD. Thank you.' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 05:24:27
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
Query 'Per GCL LAB reconciliation: Saliva: Sample dated 19JAN2021 is missing in PPD. Please provide the Accession # and Tracking number with the shipping date to track the sample in PPD. Thank you.' answered with 'updated on day 3 ' (Site from DM).	Pamela Fidler (b) (4)	24 Mar 2021 20:42:09

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Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 14:47:42

[Date of Collection](#)

Audit	User	Time (GMT)
User opened query 'Per GCL LAB reconciliation: Saliva: Sample dated 19JAN2021 is missing in PPD. Please provide the Accession # and Tracking number with the shipping date to track the sample in PPD. Thank you.' (Site from DM). User entered '19 Jan 2021'	(b) (4), (b) (6) (b) (4) Pamela Fidler (b) (4) (b) (4) (b) (4)	19 Mar 2021 07:23:28 09 Mar 2021 18:52:36

US3012171

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 14:47:42

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:27
User accepted default value 'Day 7 (Day 7)'	Pamela Fidler (b) (4)	09 Mar 2021 18:52:36

US3012171

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 14:47:42

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:27
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Pamela Fidler (b) (4)	09 Mar 2021 18:52:36

US3012171

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 14:47:42

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:27
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered empty.	(b) (4)	09 Mar 2021 18:52:36
	Pamela Fidler (b) (4)	

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Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 14:47:42

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:27
User accepted default value 'Day 9 (Day 9)'	Pamela Fidler (b) (4)	09 Mar 2021 18:52:36

US3012171

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 14:47:42

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:27
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Pamela Fidler (b) (4)	09 Mar 2021 18:52:36

US3012171

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 14:47:42

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:27
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered empty.	(b) (4)	09 Mar 2021 18:52:36
	Pamela Fidler (b) (4)	

US3012171

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 14:47:42

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:27
User accepted default value 'Day 14 (Day 14)'	Pamela Fidler (b) (4)	09 Mar 2021 18:52:36

US3012171

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 14:47:42

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:27
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Pamela Fidler (b) (4)	09 Mar 2021 18:52:36

US3012171

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 14:47:42

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:27
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered empty.	(b) (4)	09 Mar 2021 18:52:36
	Pamela Fidler (b) (4)	

US3012171

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 14:47:42

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:27
User accepted default value 'Day 21 (Day 21)'	Pamela Fidler (b) (4)	09 Mar 2021 18:52:36

US3012171

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 14:47:42

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:27
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Pamela Fidler (b) (4)	09 Mar 2021 18:52:36

US3012171

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 14:47:42

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:27
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered empty.	(b) (4)	09 Mar 2021 18:52:36
	Pamela Fidler (b) (4)	

US3012171

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 14:47:42

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:27
User accepted default value 'Day 28 (Day 28)'	Pamela Fidler (b) (4)	09 Mar 2021 18:52:36

US3012171

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 14:47:42

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:27
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Pamela Fidler (b) (4)	09 Mar 2021 18:52:36

US3012171

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 14:47:42

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:27
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered empty.	(b) (4)	09 Mar 2021 18:52:36
	Pamela Fidler (b) (4)	

US3012171

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:47:42

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:27
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Yes (Y)'	(b) (4)	09 Mar 2021 18:50:52
	Pamela Fidler (b) (4)	

US3012171

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:47:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:27
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered '15 Jan 2021'	(b) (4)	09 Mar 2021 18:50:52
	Pamela Fidler (b) (4)	

US3012171

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:47:42

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:27
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Clinic (Clinic)'	(b) (4) Pamela Fidler (b) (4)	09 Mar 2021 18:50:52

US3012171

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:47:42

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:27
User entered 'SICKD1'	System	09 Mar 2021 18:50:52

US3012171

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:47:42

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:27
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Yes (Y)'	(b) (4) Pamela Fidler (b) (4)	09 Mar 2021 18:51:18

US3012171

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:47:42

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:27
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered '15 Jan 2021'	(b) (4) Pamela Fidler (b) (4)	09 Mar 2021 18:51:18

US3012171

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:47:42

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:27
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered '15:10'	(b) (4) Pamela Fidler (b) (4)	09 Mar 2021 18:51:18

US3012171

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:47:42

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:27
User entered '15 Jan 2021 15:10'	System	09 Mar 2021 18:51:18

US3012171

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:47:42

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:27
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered '67' in	(b) (4) Pamela Fidler (b) (4)	09 Mar 2021 18:51:18
DataPoint set to visible.	System	09 Mar 2021 18:50:52

US3012171

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:47:42

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:27
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered '241.6' lb	(b) (4) Pamela Fidler (b) (4)	09 Mar 2021 18:51:18
DataPoint set to visible.	System	09 Mar 2021 18:50:52

US3012171

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:47:42

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:27
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered '98.1' F	(b) (4) Pamela Fidler (b) (4)	09 Mar 2021 18:51:18

US3012171

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:47:42

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:27
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Oral (Oral)'	(b) (4)	09 Mar 2021 18:51:18
	Pamela Fidler (b) (4)	

US3012171

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:47:42

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:27
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered empty.	(b) (4)	09 Mar 2021 18:51:18
	Pamela Fidler (b) (4)	

US3012171

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:47:42

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:27
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered '92'	(b) (4)	09 Mar 2021 18:51:18
	Pamela Fidler (b) (4)	

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Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:47:42

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:27
User entered 'bpm'	System	09 Mar 2021 18:51:18

US3012171

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:47:42

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:27
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered '14'	(b) (4) Pamela Fidler (b) (4)	09 Mar 2021 18:51:18

US3012171

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:47:42

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:27
User entered 'breaths/min'	System	09 Mar 2021 18:51:18

US3012171

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:47:42

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:27
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered '122'	(b) (4) Pamela Fidler (b) (4)	09 Mar 2021 18:51:18

US3012171

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:47:42

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:27
User entered 'mmHg'	System	09 Mar 2021 18:51:18

US3012171

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:47:42

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:27
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered '78'	(b) (4) Pamela Fidler (b) (4)	09 Mar 2021 18:51:18

US3012171

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:47:42

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:27
User entered 'mmHg'	System	09 Mar 2021 18:51:18

US3012171

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:47:42

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:27

US3012171

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:47:42

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:27

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Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:47:42

[Was the physical examination performed?](#)

(b)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:27
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Yes (Y)'	(b) (4) Pamela Fidler (b) (4)	09 Mar 2021 18:51:23

US3012171

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:47:42

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:27
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered '15 Jan 2021'	(b) (4)	09 Mar 2021 18:51:23
	Pamela Fidler (b) (4)	

US3012171

Folder: Illness Visit Day 1 (1)

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

Generated On: 09 Jun 2021 14:47:42

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:27
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Yes (Y)'	(b) (4) Pamela Fidler (b) (4)	09 Mar 2021 18:51:34

US3012171

Folder: Illness Visit Day 1 (1)

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

Generated On: 09 Jun 2021 14:47:42

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:27
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered '15 Jan 2021'	(b) (4) Pamela Fidler (b) (4)	09 Mar 2021 18:51:34

US3012171

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

Form: Visit Date

Generated On: 09 Jun 2021 14:47:42

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:28:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Yes (Y)'	(b) (4) Pamela Fidler (b) (4)	11 Mar 2021 22:15:38

US3012171

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

Form: Visit Date

Generated On: 09 Jun 2021 14:47:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:28:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered '11 Mar 2021'	(b) (4)	11 Mar 2021 22:15:38
	Pamela Fidler (b) (4)	

US3012171

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

Form: Visit Date

Generated On: 09 Jun 2021 14:47:42

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:28:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Clinic (Clinic)'	(b) (4) Pamela Fidler (b) (4)	11 Mar 2021 22:15:38

US3012171

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

Form: Visit Date

Generated On: 09 Jun 2021 14:47:42

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:28:48
User entered 'UNBLND_DECIDE'	System	11 Mar 2021 22:15:38

US3012171

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

Form: Unblinding

Generated On: 09 Jun 2021 14:47:42

[Date of updated informed consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:28:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered '11 Mar 2021'	(b) (4) Pamela Fidler (b) (4)	11 Mar 2021 22:15:51

US3012171

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

Form: Unblinding

Generated On: 09 Jun 2021 14:47:42

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:28:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered '0'	(b) (4) Pamela Fidler (b) (4)	11 Mar 2021 22:15:51

US3012171

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

Form: Unblinding

Generated On: 09 Jun 2021 14:47:42

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:28:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Yes (Y)'	(b) (4)	11 Mar 2021 22:15:51
	Pamela Fidler (b) (4)	

US3012171

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

Form: Unblinding

Generated On: 09 Jun 2021 14:47:42

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:28:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4) Pamela Fidler (b) (4)	11 Mar 2021 22:15:51

US3012171

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

Form: Unblinding

Generated On: 09 Jun 2021 14:47:42

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:28:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered '11 Mar 2021'	(b) (4) Pamela Fidler (b) (4)	11 Mar 2021 22:15:51

US3012171

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

Form: Unblinding

Generated On: 09 Jun 2021 14:47:42

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:28:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Pamela Fidler (b) (4)	11 Mar 2021 22:15:51

US3012171

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

Form: Unblinding

Generated On: 09 Jun 2021 14:47:42

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:28:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Pamela Fidler (b) (4)	11 Mar 2021 22:15:51

US3012171

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

Form: Unblinding

Generated On: 09 Jun 2021 14:47:42

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:28:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Pamela Fidler (b) (4)	11 Mar 2021 22:15:51

US3012171

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

Form: Unblinding

Generated On: 09 Jun 2021 14:47:42

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:28:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'No (N)'	(b) (4)	11 Mar 2021 22:15:51
	Pamela Fidler (b) (4)	

US3012171

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

Form: Unblinding

Generated On: 09 Jun 2021 14:47:42

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:28:48
User entered empty.	System	11 Mar 2021 22:15:51

US3012171

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

Form: Unblinding

Generated On: 09 Jun 2021 14:47:42

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:28:48
User entered empty.	System	11 Mar 2021 22:15:51

US3012171

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:47:42

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:28:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Yes (Y)'	(b) (4) Pamela Fidler (b) (4)	11 Mar 2021 22:16:12

US3012171

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:47:42

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:28:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered '11 Mar 2021'	(b) (4) Pamela Fidler (b) (4)	11 Mar 2021 22:16:12

US3012171

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:47:42

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:28:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered '11:44'	(b) (4) Pamela Fidler (b) (4)	11 Mar 2021 22:16:12

US3012171

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:47:42

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:28:48
User entered '11 Mar 2021 11:44'	System	11 Mar 2021 22:16:12

US3012171

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 14:47:42

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:28:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Yes (Y)'	(b) (4) Pamela Fidler (b) (4)	11 Mar 2021 22:16:20

US3012171

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 14:47:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:28:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered '11 Mar 2021'	(b) (4) Pamela Fidler (b) (4)	11 Mar 2021 22:16:20

US3012171

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 14:47:42

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:28:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered '11:38'	(b) (4) Pamela Fidler (b) (4)	11 Mar 2021 22:16:20

US3012171

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 14:47:42

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:28:48
User entered '11 Mar 2021 11:38'	System	11 Mar 2021 22:16:20

US3012171

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 14:47:42

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:53:20
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:07:36
User signature succeeded.	Laurence Chu (b) (4)	18 Mar 2021 23:04:48
Signature has been broken.	(b) (4) Jennifer Leyva (b) (4)	15 Mar 2021 20:54:43
User entered 'Yes (Y)' reason for change: New Information	(b) (4) Jennifer Leyva (b) (4)	15 Mar 2021 20:54:43
User signature succeeded.	Laurence Chu (b) (4)	12 Mar 2021 19:36:07
User entered 'No (N)'	(b) (4) Jennifer Leyva (b) (4)	19 Aug 2020 15:31:34

US3012171

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:47:42

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:28:31
User signature succeeded.	Laurence Chu (b) (4)	18 Mar 2021 23:04:48
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 14:52:32
User entered		
'USA-US006-2021-mRNA-1273-P301000007'	System	16 Mar 2021 14:52:20
User entered 'New'	(b) (4), (b) (6)	16 Mar 2021 14:52:20

US3012171

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:47:42

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:28:32
User signature succeeded.	Laurence Chu (b) (4)	18 Mar 2021 23:04:48
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)	15 Mar 2021 21:04:33
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	15 Mar 2021 21:04:33
Data point term sent to Coder	System	15 Mar 2021 21:03:49
User entered 'Urinary Tract Infection'	Jennifer Leyva (b) (4)	15 Mar 2021 21:03:35

US3012171

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:47:42

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:28:34
User signature succeeded.	Laurence Chu (b) (4)	18 Mar 2021 23:04:48
User entered 'Yes (Y)'	Jennifer Leyva (b) (4)	15 Mar 2021 21:03:35

US3012171

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:47:42

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:28:43
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 19:28:39
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:28:37
User signature succeeded.	Laurence Chu (b) (4)	18 Mar 2021 23:04:48
User entered 'No (N)'	Jennifer Leyva (b) (4)	15 Mar 2021 21:03:35

US3012171

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:47:42

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:28:45
User signature succeeded.	Laurence Chu (b) (4)	18 Mar 2021 23:04:48
User entered 'No (N)'	Jennifer Leyva (b) (4)	15 Mar 2021 21:03:35

US3012171

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:47:42

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:28:46
User signature succeeded.	Laurence Chu (b) (4)	18 Mar 2021 23:04:48
User entered '12 Mar 2021'	Jennifer Leyva (b) (4)	15 Mar 2021 21:03:35

US3012171

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:47:42

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:28:48
User signature succeeded.	Laurence Chu (b) (4)	18 Mar 2021 23:04:48
User entered empty.	Jennifer Leyva (b) (4)	15 Mar 2021 21:03:35

US3012171

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:47:42

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Mar 2021 21:03:35

US3012171

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:47:42

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	15 Apr 2021 16:35:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 19:28:58
Signature has been broken.	(b) (4), (b) (6)	12 Apr 2021 17:57:33
User entered 'No (N)' reason for change: Data Entry Error		12 Apr 2021 17:57:33
User signature succeeded.	Laurence Chu (b) (4)	18 Mar 2021 23:04:48
	(b) (4)	
User entered 'Yes (Y)'	Jennifer Leyva (b) (4)	15 Mar 2021 21:03:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:47:42

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	15 Apr 2021 16:35:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 22:46:24
User closed query 'Per source, SAE stop date is 13Apr2021. Please verify and update EDC accordingly.' (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 22:46:22
Query 'Per source, SAE stop date is 13Apr2021. Please verify and update EDC accordingly.' answered with 'Updated' (Site from CRA).	Jennifer Leyva (b) (4)	13 Apr 2021 21:17:25
User entered '13 Apr 2021' reason for change: Data Entry Error	Jennifer Leyva (b) (4)	13 Apr 2021 21:17:06
User opened query 'Per source, SAE stop date is 13Apr2021. Please verify and update EDC accordingly.' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 19:29:41
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	12 Apr 2021 17:58:01
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	12 Apr 2021 17:58:01
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	12 Apr 2021 17:57:33
Signature has been broken.	(b) (4), (b) (6)	12 Apr 2021 17:57:33
User entered '12 Apr 2021' reason for change: Data Entry Error		12 Apr 2021 17:57:33
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).		25 Mar 2021 14:41:59
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'ongoing' (Site from Safety).	Pamela Fidler (b) (4)	24 Mar 2021 20:29:56

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:47:42

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	24 Mar 2021 19:54:20
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	24 Mar 2021 16:22:48
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'Will update when information becomes available' (Site from Safety).	Pamela Fidler (b) (4)	23 Mar 2021 16:24:23
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	23 Mar 2021 15:36:21
User signature succeeded.	Laurence Chu (b) (4)	18 Mar 2021 23:04:48
User entered empty.	(b) (4) Jennifer Leyva (b) (4) (b) (4)	15 Mar 2021 21:03:35

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:47:42

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:29:48
User signature succeeded.	Laurence Chu (b) (4)	18 Mar 2021 23:04:48
User entered empty.	Jennifer Leyva (b) (4)	15 Mar 2021 21:03:35

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:47:42

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Mar 2021 21:03:35

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:47:42

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:29:53
User signature succeeded.	Laurence Chu (b) (4)	18 Mar 2021 23:04:48
User entered 'Grade 1/Mild (Grade 1/Mild)'	Jennifer Leyva (b) (4)	15 Mar 2021 21:03:35

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:47:42

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:29:55
User signature succeeded.	Laurence Chu (b) (4)	18 Mar 2021 23:04:48
User entered 'Yes (Y)'	Jennifer Leyva (b) (4)	15 Mar 2021 21:03:35

US3012171

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:47:42

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:29:57
User signature succeeded.	Laurence Chu (b) (4)	18 Mar 2021 23:04:48
User entered '0'	Jennifer Leyva (b) (4)	15 Mar 2021 21:03:35

US3012171

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:47:42

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:29:59
User signature succeeded.	Laurence Chu (b) (4)	18 Mar 2021 23:04:48
User entered '0'	Jennifer Leyva (b) (4)	15 Mar 2021 21:03:35

US3012171

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:47:42

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:30:18
User closed query 'PV Query: Please consider clarifying what type of antibiotics were used for treatment. Please leave query open until information is available. If information is unable to be obtained, please state so in your response.' (Site from Safety).	(b) (4), (b) (6)	09 Apr 2021 13:37:28
Query 'PV Query: Please consider clarifying what type of antibiotics were used for treatment. Please leave query open until information is available. If information is unable to be obtained, please state so in your response.' answered with 'Updated' (Site from Safety).	Pamela Fidler (b) (4)	08 Apr 2021 19:39:47
User opened query 'PV Query: Please consider clarifying what type of antibiotics were used for treatment. Please leave query open until information is available. If information is unable to be obtained, please state so in your response.' (Site from Safety).	(b) (4), (b) (6)	06 Apr 2021 20:25:33
User closed query 'PV Query: Please consider clarifying what type of antibiotics were used for treatment.' (Site from Safety).	(b) (4), (b) (6)	06 Apr 2021 20:25:33
Query 'PV Query: Please consider clarifying what type of antibiotics were used for treatment.' answered with 'Unknown at this time, pending hospital paperwork' (Site from Safety).	Jennifer Leyva (b) (4)	05 Apr 2021 21:10:09
User opened query 'PV Query: Please consider clarifying what type of antibiotics were used for treatment.' (Site from Safety).	(b) (4), (b) (6)	02 Apr 2021 20:37:47
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)	26 Mar 2021 01:52:49
User signature succeeded.	Laurence Chu (b) (4)	18 Mar 2021 23:04:48
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 'Discharge date pending' (Site from System).	Jennifer Leyva (b) (4)	15 Mar 2021 21:07:45

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:47:42

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
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). User entered 'I'	System	15 Mar 2021 21:03:35
	Jennifer Leyva (b) (4) (b) (4)	15 Mar 2021 21:03:35

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:47:42

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:30:40
User signature succeeded.	Laurence Chu (b) (4)	18 Mar 2021 23:04:48
User entered '12 Mar 2021'	Jennifer Leyva (b) (4)	15 Mar 2021 21:03:35

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:47:42

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:31:24
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User closed query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	25 Mar 2021 14:42:02
Query 'PV Query: Please provide the hospital discharge date when available.' answered with 'updated' (Site from Safety).	Pamela Fidler (b) (4)	24 Mar 2021 20:30:57
Signature has been broken.	Pamela Fidler (b) (4)	24 Mar 2021 20:30:40
User entered '17 Mar 2021' reason for change: Data Entry Error	Pamela Fidler (b) (4)	24 Mar 2021 20:30:40
User opened query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	24 Mar 2021 19:54:11
User closed query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	24 Mar 2021 16:22:56
Query 'PV Query: Please provide the hospital discharge date when available.' answered with 'Will update when information is received' (Site from Safety).	Pamela Fidler (b) (4)	23 Mar 2021 16:23:15
User opened query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	23 Mar 2021 15:35:53
User signature succeeded.	Laurence Chu (b) (4)	18 Mar 2021 23:04:48
User entered empty.	Jennifer Leyva (b) (4)	15 Mar 2021 21:03:35

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:47:42

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:31:26
User signature succeeded.	Laurence Chu (b) (4)	18 Mar 2021 23:04:48
User entered 'No (N)'	Jennifer Leyva (b) (4)	15 Mar 2021 21:03:35

US3012171

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:47:42

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:31:28
User signature succeeded.	Laurence Chu (b) (4)	18 Mar 2021 23:04:48
User entered empty.	Jennifer Leyva (b) (4)	15 Mar 2021 21:03:35

US3012171

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:47:42

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:31:29
User signature succeeded.	Laurence Chu (b) (4)	18 Mar 2021 23:04:48
User entered '0'	Jennifer Leyva (b) (4)	15 Mar 2021 21:03:35

US3012171

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:47:42

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:31:32
User signature succeeded.	Laurence Chu (b) (4)	18 Mar 2021 23:04:48
User entered '0'	Jennifer Leyva (b) (4)	15 Mar 2021 21:03:35

US3012171

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:47:42

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:31:33
User signature succeeded.	Laurence Chu (b) (4)	18 Mar 2021 23:04:48
User entered '0'	Jennifer Leyva (b) (4)	15 Mar 2021 21:03:35

US3012171

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:47:42

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:31:43
User signature succeeded.	Laurence Chu (b) (4)	18 Mar 2021 23:04:48
User entered 'Not Related (NOT RELATED)'	Jennifer Leyva (b) (4)	15 Mar 2021 21:03:35

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:47:42

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:31:45
User signature succeeded.	Laurence Chu (b) (4)	18 Mar 2021 23:04:48
User entered 'Not Related (NOT RELATED)'	Jennifer Leyva (b) (4)	15 Mar 2021 21:03:35

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:47:42

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:31:47
User signature succeeded.	Laurence Chu (b) (4)	18 Mar 2021 23:04:48
User entered 'Not Applicable (NOT APPLICABLE)'	Jennifer Leyva (b) (4)	15 Mar 2021 21:03:35

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:47:42

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:31:48
User signature succeeded.	Laurence Chu (b) (4)	18 Mar 2021 23:04:48
User entered '0'	Jennifer Leyva (b) (4)	15 Mar 2021 21:03:35

US3012171

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:47:42

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:31:50
User signature succeeded.	Laurence Chu (b) (4)	18 Mar 2021 23:04:48
User entered 'I'	Jennifer Leyva (b) (4)	15 Mar 2021 21:03:35

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:47:42

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:31:57
User signature succeeded.	Laurence Chu (b) (4)	18 Mar 2021 23:04:48
User entered '0'	Jennifer Leyva (b) (4)	15 Mar 2021 21:03:35

US3012171

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:47:42

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	15 Apr 2021 16:35:55
DataPoint Verified.	(b) (4)	13 Apr 2021 19:31:53
Signature has been broken.	(b) (4), (b) (6)	12 Apr 2021 17:58:01
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error		12 Apr 2021 17:58:01
User closed query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).		25 Mar 2021 14:42:06
Query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' answered with 'ongoing' (Site from Safety).	Pamela Fidler (b) (4)	24 Mar 2021 20:31:17
User opened query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4), (b) (6)	24 Mar 2021 19:54:32
User closed query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4), (b) (6)	24 Mar 2021 16:23:00
Query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' answered with 'Will update when information becomes available. We do not keep queries open' (Site from Safety).	Pamela Fidler (b) (4)	23 Mar 2021 16:24:50
User opened query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4), (b) (6)	23 Mar 2021 15:36:55
User signature succeeded.	Laurence Chu (b) (4)	18 Mar 2021 23:04:48
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Jennifer Leyva (b) (4)	15 Mar 2021 21:03:35

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:47:42

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:31:55
User signature succeeded.	Laurence Chu (b) (4)	18 Mar 2021 23:04:48
User entered empty.	Jennifer Leyva (b) (4)	15 Mar 2021 21:03:35

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:47:42

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so. ' (Site from Safety).	(b) (4), (b) (6)	30 Apr 2021 14:05:52
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. ' (Site from Safety).	(b) (4), (b) (6)	30 Apr 2021 14:05:51
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 'No COVID-19 testing listed in medical records' (Site from Safety).	Jennifer Leyva (b) (4) (b) (4)	29 Apr 2021 19:18:28
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. ' answered with 'All medical records received have been sent to Safety Team via email.' (Site from Safety).	Jennifer Leyva (b) (4) (b) (4)	29 Apr 2021 19:17:57
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. ' (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 18:56:48
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so. ' (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 18:56:40
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:32:00
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	25 Mar 2021 14:42:13
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	25 Mar 2021 14:42:09

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:47:42

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'awaiting medical records' (Site from Safety).	Pamela Fidler (b) (4)	24 Mar 2021 20:31:56
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 'Awaiting medical records' (Site from Safety).	Pamela Fidler (b) (4)	24 Mar 2021 20:31:40
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	24 Mar 2021 19:54:26
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	24 Mar 2021 19:54:05
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. ' (Site from Safety).	(b) (4), (b) (6)	24 Mar 2021 16:23:05
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so. ' (Site from Safety).	(b) (4), (b) (6)	24 Mar 2021 16:23:02
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 'Will update when information becomes available' (Site from Safety).	Pamela Fidler (b) (4)	23 Mar 2021 16:25:05
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. ' answered with 'Will update when information becomes available' (Site from Safety).	Pamela Fidler (b) (4)	23 Mar 2021 16:24:11
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. ' (Site from Safety).	(b) (4), (b) (6)	23 Mar 2021 15:36:40

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so. ' (Site from Safety).	(b) (4), (b) (6)	23 Mar 2021 15:34:38
User signature succeeded.	Laurence Chu (b) (4)	18 Mar 2021 23:04:48
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	(b) (4)	15 Mar 2021 21:07:56
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	15 Mar 2021 21:07:56
User entered 'Pt reported to ER on 12-Mar-2021 due to severe pain in abdomen. Diagnosed with Urinary Tract infection and Bladder Infection.' reason for change: Data Entry Error	Jennifer Leyva (b) (4)	15 Mar 2021 21:07:56
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	15 Mar 2021 21:03:35
User entered empty.	Jennifer Leyva (b) (4)	15 Mar 2021 21:03:35

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:47:42

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	15 Mar 2021 21:03:35

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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	15 Mar 2021 21:03:35

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:47:42

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	15 Mar 2021 21:03:35

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:47:42

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:33:23
User signature succeeded.	Laurence Chu (b) (4)	18 Mar 2021 23:04:48
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 14:53:08
User entered 'USA-US006-2021-mRNA-1273-P301000007'	(b) (4), (b) (6)	16 Mar 2021 14:53:05

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:47:42

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	15 Apr 2021 16:35:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 22:46:35
	(b) (4), (b) (6)	14 Apr 2021 22:46:34
User closed query 'Per source, the event diagnosis is recorded as, Leukocytosis. Please verify with source, and update EDC accordingly.' (Site from CRA).		
User coded data point as SOC: Blood and lymphatic system disorders, HLGT: White blood cell disorders, HLT: Leukocytoses NEC, PT: Leukocytosis, LLT: Leukocytosis - version MedDRA\\23.0.	Coder Import (b) (4)	13 Apr 2021 21:19:40
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Apr 2021 21:19:40
	(b) (4)	
Query 'Per source, the event diagnosis is recorded as, Leukocytosis. Please verify with source, and update EDC accordingly.' answered with 'Updated' (Site from CRA).	Jennifer Leyva (b) (4)	13 Apr 2021 21:18:54
	(b) (4)	
Data point term sent to Coder	System	13 Apr 2021 21:18:47
Coding entries removed.	Jennifer Leyva (b) (4)	13 Apr 2021 21:18:41
	(b) (4)	
Signature has been broken.	Jennifer Leyva (b) (4)	13 Apr 2021 21:18:41
	(b) (4)	
User entered 'LEUKOCYTOSIS' reason for change: Data Entry Error	Jennifer Leyva (b) (4)	13 Apr 2021 21:18:41
	(b) (4)	
User opened query 'Per source, the event diagnosis is recorded as, Leukocytosis. Please verify with source, and update EDC accordingly.' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 19:37:47
User signature succeeded.	Laurence Chu (b) (4)	18 Mar 2021 23:04:48
	(b) (4)	
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Urinary tract infections, PT: Cystitis, LLT: Bladder infection - version MedDRA\\23.0.	Coder Import (b) (4)	15 Mar 2021 21:06:42
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	15 Mar 2021 21:06:42
	(b) (4)	
Data point term sent to Coder	System	15 Mar 2021 21:05:51
User entered 'Bladder Infection'	Jennifer Leyva (b) (4)	15 Mar 2021 21:05:04
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

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[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:37:49
User signature succeeded.	Laurence Chu (b) (4)	18 Mar 2021 23:04:48
User entered 'Yes (Y)'	Jennifer Leyva (b) (4)	15 Mar 2021 21:05:04

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:47:42

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:37:51
User signature succeeded.	Laurence Chu (b) (4)	18 Mar 2021 23:04:48
User entered 'No (N)'	Jennifer Leyva (b) (4)	15 Mar 2021 21:05:04

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Folder: Adverse Events

Form: Adverse Events (2)

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:37:54
User signature succeeded.	Laurence Chu (b) (4)	18 Mar 2021 23:04:48
User entered 'No (N)'	Jennifer Leyva (b) (4)	15 Mar 2021 21:05:04

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:47:42

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:37:56
User signature succeeded.	Laurence Chu (b) (4)	18 Mar 2021 23:04:48
User entered '12 Mar 2021'	Jennifer Leyva (b) (4)	15 Mar 2021 21:05:04

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:47:42

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:37:58
User signature succeeded.	Laurence Chu (b) (4)	18 Mar 2021 23:04:48
User entered empty.	Jennifer Leyva (b) (4)	15 Mar 2021 21:05:04

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Folder: Adverse Events

Form: Adverse Events (2)

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[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Mar 2021 21:05:04

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:47:42

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	15 Apr 2021 16:35:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 19:37:59
Signature has been broken.	(b) (4), (b) (6)	12 Apr 2021 17:58:51
User entered 'No (N)' reason for change: Data Entry Error		12 Apr 2021 17:58:51
User signature succeeded.	Laurence Chu (b) (4)	18 Mar 2021 23:04:48
	(b) (4)	
User entered 'Yes (Y)'	Jennifer Leyva (b) (4)	15 Mar 2021 21:05:04
	(b) (4)	

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Folder: Adverse Events

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	15 Apr 2021 16:35:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 22:46:40
User closed query 'Per source, SAE end date is recorded as, 13Apr2021. Please verify and update EDC accordingly.' (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 22:46:39
Query 'Per source, SAE end date is recorded as, 13Apr2021. Please verify and update EDC accordingly.' answered with 'Updated' (Site from CRA).	Jennifer Leyva (b) (4)	13 Apr 2021 21:19:06
	(b) (4)	
User entered '13 Apr 2021' reason for change: Data Entry Error	Jennifer Leyva (b) (4)	13 Apr 2021 21:18:41
	(b) (4)	
User opened query 'Per source, SAE end date is recorded as, 13Apr2021. Please verify and update EDC accordingly.' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 19:38:29
Signature has been broken.	Lisa Johnson (b) (4)	12 Apr 2021 17:58:51
User entered '12 Apr 2021' reason for change: Data Entry Error	Lisa Johnson (b) (4)	12 Apr 2021 17:58:51
User signature succeeded.	Laurence Chu (b) (4)	18 Mar 2021 23:04:48
	(b) (4)	
User entered empty.	Jennifer Leyva (b) (4)	15 Mar 2021 21:05:04
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

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[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:38:31
User signature succeeded.	Laurence Chu (b) (4)	18 Mar 2021 23:04:48
User entered empty.	Jennifer Leyva (b) (4)	15 Mar 2021 21:05:04

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:47:42

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Mar 2021 21:05:04

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Folder: Adverse Events

Form: Adverse Events (2)

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[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:38:33
User signature succeeded.	Laurence Chu (b) (4)	18 Mar 2021 23:04:48
User entered 'Grade 1/Mild (Grade 1/Mild)'	Jennifer Leyva (b) (4)	15 Mar 2021 21:05:04

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:47:42

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:38:34
User signature succeeded.	Laurence Chu (b) (4)	18 Mar 2021 23:04:48
User entered 'Yes (Y)'	Jennifer Leyva (b) (4)	15 Mar 2021 21:05:04

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:47:42

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:38:36
User signature succeeded.	Laurence Chu (b) (4)	18 Mar 2021 23:04:48
User entered '0'	Jennifer Leyva (b) (4)	15 Mar 2021 21:05:04

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:47:42

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:38:38
User signature succeeded.	Laurence Chu (b) (4)	18 Mar 2021 23:04:48
User entered '0'	Jennifer Leyva (b) (4)	15 Mar 2021 21:05:04

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:47:42

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:38:39
User closed query 'Per CDM Re-query: Please update the discharge date once available.' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 10:33:01
Query 'Per CDM Re-query: Please update the discharge date once available.' answered with 'updated' (Site from DM).	Pamela Fidler (b) (4)	26 Mar 2021 14:59:46
User opened query 'Per CDM Re-query: Please update the discharge date once available.' (Site from DM).	(b) (4), (b) (6)	26 Mar 2021 01:53:44
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)	26 Mar 2021 01:53:13
User signature succeeded.	Laurence Chu (b) (4)	18 Mar 2021 23:04:48
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 'Discharge date pending' (Site from System).	Jennifer Leyva (b) (4)	15 Mar 2021 21:07:34
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	15 Mar 2021 21:05:04
User entered '1'	Jennifer Leyva (b) (4)	15 Mar 2021 21:05:04

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Folder: Adverse Events

Form: Adverse Events (2)

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Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:38:41
User signature succeeded.	Laurence Chu (b) (4)	18 Mar 2021 23:04:48
User entered '12 Mar 2021'	Jennifer Leyva (b) (4)	15 Mar 2021 21:05:04

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:47:42

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:38:43
User signature succeeded.	Laurence Chu (b) (4)	09 Apr 2021 20:42:01
Signature has been broken.	(b) (4) Pamela Fidler (b) (4)	26 Mar 2021 14:59:40
User entered '17 Mar 2021' reason for change: Data Entry Error	Pamela Fidler (b) (4)	26 Mar 2021 14:59:40
User signature succeeded.	Laurence Chu (b) (4)	18 Mar 2021 23:04:48
User entered empty.	(b) (4) Jennifer Leyva (b) (4)	15 Mar 2021 21:05:04

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:47:42

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:38:44
User signature succeeded.	Laurence Chu (b) (4)	18 Mar 2021 23:04:48
User entered 'No (N)'	Jennifer Leyva (b) (4)	15 Mar 2021 21:05:04

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Folder: Adverse Events

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:38:46
User signature succeeded.	Laurence Chu (b) (4)	18 Mar 2021 23:04:48
User entered empty.	Jennifer Leyva (b) (4)	15 Mar 2021 21:05:04

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Folder: Adverse Events

Form: Adverse Events (2)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:38:48
User signature succeeded.	Laurence Chu (b) (4)	18 Mar 2021 23:04:48
User entered '0'	Jennifer Leyva (b) (4)	15 Mar 2021 21:05:04

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Folder: Adverse Events

Form: Adverse Events (2)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:38:49
User signature succeeded.	Laurence Chu (b) (4)	18 Mar 2021 23:04:48
User entered '0'	Jennifer Leyva (b) (4)	15 Mar 2021 21:05:04

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Folder: Adverse Events

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[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:38:51
User signature succeeded.	Laurence Chu (b) (4)	18 Mar 2021 23:04:48
User entered '0'	Jennifer Leyva (b) (4)	15 Mar 2021 21:05:04

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:38:54
User signature succeeded.	Laurence Chu (b) (4)	18 Mar 2021 23:04:48
User entered 'Not Related (NOT RELATED)'	Jennifer Leyva (b) (4)	15 Mar 2021 21:05:04

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Folder: Adverse Events

Form: Adverse Events (2)

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:38:55
User signature succeeded.	Laurence Chu (b) (4)	18 Mar 2021 23:04:48
User entered 'Not Related (NOT RELATED)'	Jennifer Leyva (b) (4)	15 Mar 2021 21:05:04

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:39:00
User signature succeeded.	Laurence Chu (b) (4)	18 Mar 2021 23:04:48
User entered 'Not Applicable (NOT APPLICABLE)'	Jennifer Leyva (b) (4)	15 Mar 2021 21:05:04

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Folder: Adverse Events

Form: Adverse Events (2)

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[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:39:04
User signature succeeded.	Laurence Chu (b) (4)	18 Mar 2021 23:04:48
User entered '0'	Jennifer Leyva (b) (4)	15 Mar 2021 21:05:04

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Folder: Adverse Events

Form: Adverse Events (2)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:39:06
User signature succeeded.	Laurence Chu (b) (4)	18 Mar 2021 23:04:48
User entered 'I'	Jennifer Leyva (b) (4)	15 Mar 2021 21:05:04

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Folder: Adverse Events

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:39:07
User signature succeeded.	Laurence Chu (b) (4)	18 Mar 2021 23:04:48
User entered '0'	Jennifer Leyva (b) (4)	15 Mar 2021 21:05:04

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[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	15 Apr 2021 16:35:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 19:39:10
Signature has been broken.	(b) (4), (b) (6)	12 Apr 2021 17:58:51
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error		12 Apr 2021 17:58:51
User signature succeeded.	Laurence Chu (b) (4)	18 Mar 2021 23:04:48
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4)	
	Jennifer Leyva (b) (4)	15 Mar 2021 21:05:04
	(b) (4)	

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:39:24
User signature succeeded.	Laurence Chu (b) (4)	18 Mar 2021 23:04:48
User entered empty.	Jennifer Leyva (b) (4)	15 Mar 2021 21:05:04

US3012171

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:47:42

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:39:26
User signature succeeded.	Laurence Chu (b) (4)	18 Mar 2021 23:04:48
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	(b) (4) System	15 Mar 2021 21:07:13
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	15 Mar 2021 21:07:13
User entered 'Pt reported to ER on 12-Mar-2021 due to severe pain in abdomen. Diagnosed with Urinary Tract infection and Bladder Infection. Pt due to be discharged 16-Mar-2021.' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	15 Mar 2021 21:07:13
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	15 Mar 2021 21:05:04
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	15 Mar 2021 21:05:04

US3012171

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:47:42

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Mar 2021 21:05:04

US3012171

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:47:42

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	15 Mar 2021 21:05:04

US3012171

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:47:42

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	15 Mar 2021 21:05:04

US3012171

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:47:42

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	15 Apr 2021 16:35:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 19:42:44
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 17:24:30
User entered	(b) (4), (b) (6)	13 Apr 2021 17:24:08
'USA-US006-2021-mRNA-1273-P301000007'		

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:47:42

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	15 Apr 2021 16:35:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 19:43:22
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Male reproductive tract infections, PT: Epididymitis, LLT: Epididymitis - version MedDRA\\23.0.	Coder Import (b) (4)	12 Apr 2021 18:28:01
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	12 Apr 2021 18:28:01
Data point term sent to Coder	System	12 Apr 2021 17:57:27
User entered 'epididymitis'	(b) (4), (b) (6)	12 Apr 2021 17:56:52

US3012171

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:47:42

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	15 Apr 2021 16:35:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:43:24
User entered 'Yes (Y)'		12 Apr 2021 17:56:52

US3012171

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:47:42

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	15 Apr 2021 16:35:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:43:28
User entered 'No (N)'		12 Apr 2021 17:56:52

US3012171

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:47:42

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	15 Apr 2021 16:35:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:43:29
User entered 'No (N)'		12 Apr 2021 17:56:52

US3012171

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:47:42

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

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	15 Apr 2021 16:35:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:43:31
User entered '12 Mar 2021'		12 Apr 2021 17:56:52

US3012171

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:47:42

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	15 Apr 2021 16:35:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 19:43:33
User entered empty.	(b) (4), (b) (6)	12 Apr 2021 17:56:52

US3012171

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:47:42

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Apr 2021 17:56:52

US3012171

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:47:42

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	15 Apr 2021 16:35:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 19:43:34
User entered 'No (N)'	(b) (4), (b) (6)	12 Apr 2021 17:56:52

US3012171

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:47:42

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	15 Apr 2021 16:35:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 22:46:52
User closed query 'Per source, end date is recorded as, 13Apr2021. Please verify and update EDC accordingly.' (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 22:46:50
Query 'Per source, end date is recorded as, 13Apr2021. Please verify and update EDC accordingly.' answered with 'Updated' (Site from CRA).	Jennifer Leyva (b) (4)	13 Apr 2021 21:20:28
	(b) (4)	
User entered '13 Apr 2021' reason for change: Data Entry Error	Jennifer Leyva (b) (4)	13 Apr 2021 21:19:43
	(b) (4)	
User opened query 'Per source, end date is recorded as, 13Apr2021. Please verify and update EDC accordingly.' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 19:43:57
User entered '12 Apr 2021'	(b) (4), (b) (6)	12 Apr 2021 17:56:52

US3012171

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:47:42

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	15 Apr 2021 16:35:55
DataPoint Verified.	(b) (4)	13 Apr 2021 19:43:59
User entered empty.	(b) (4), (b) (6)	12 Apr 2021 17:56:52
	(b) (4), (b) (6)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:47:42

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Apr 2021 17:56:52

US3012171

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:47:42

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	15 Apr 2021 16:35:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 19:44:03
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4), (b) (6)	12 Apr 2021 17:56:52

US3012171

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:47:42

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	15 Apr 2021 16:35:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 19:44:05
User closed query 'Is the adverse event serious is No, but seriousness criteria is provided. Please correct.' (Site from System).	System	12 Apr 2021 18:02:39
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Apr 2021 18:02:39
User opened query 'Is the adverse event serious is No, but seriousness criteria is provided. Please correct.' (Site from System).	System	12 Apr 2021 18:01:56
User entered 'No (N)'	(b) (4), (b) (6)	12 Apr 2021 17:56:52

US3012171

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:47:42

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	15 Apr 2021 16:35:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 19:44:07
User entered '0'	(b) (4), (b) (6)	12 Apr 2021 17:56:52

US3012171

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:47:42

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	15 Apr 2021 16:35:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 19:44:09
User entered '0'	(b) (4), (b) (6)	12 Apr 2021 17:56:52

US3012171

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:47:42

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	15 Apr 2021 16:35:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:44:11
User closed query 'Requires inpatient or prolongation System 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).		12 Apr 2021 18:02:18
Query 'Requires inpatient or prolongation of existing System Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered by data change (Site from System).		12 Apr 2021 18:02:18
User closed query 'Requires inpatient or prolongation System of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).		12 Apr 2021 18:01:56
Query 'Requires inpatient or prolongation of existing System Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).		12 Apr 2021 18:01:56
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	12 Apr 2021 18:01:56
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Apr 2021 18:01:56
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	12 Apr 2021 18:01:44
User entered '0'	(b) (4), (b) (6)	12 Apr 2021 17:56:52

US3012171

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:47:42

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	15 Apr 2021 16:35:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 19:44:13
User entered '12 Mar 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Apr 2021 18:01:44
User entered empty.		12 Apr 2021 17:56:52

US3012171

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:47:42

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	15 Apr 2021 16:35:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 19:44:15
User entered '17 Mar 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Apr 2021 18:01:44
User entered empty.		12 Apr 2021 17:56:52

US3012171

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:47:42

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	15 Apr 2021 16:35:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:44:17
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Apr 2021 18:02:18
User entered empty.		12 Apr 2021 17:56:52

US3012171

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:47:42

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	15 Apr 2021 16:35:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 19:44:21
User entered empty.	(b) (4), (b) (6)	12 Apr 2021 17:56:52

US3012171

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:47:42

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	15 Apr 2021 16:35:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 19:44:23
User entered '0'	(b) (4), (b) (6)	12 Apr 2021 17:56:52

US3012171

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:47:42

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	15 Apr 2021 16:35:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 19:44:25
User entered '0'	(b) (4), (b) (6)	12 Apr 2021 17:56:52

US3012171

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:47:42

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	15 Apr 2021 16:35:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 19:44:27
User entered '0'	(b) (4), (b) (6)	12 Apr 2021 17:56:52

US3012171

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:47:42

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	15 Apr 2021 16:35:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 19:44:29
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	12 Apr 2021 17:56:52

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:47:42

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	15 Apr 2021 16:35:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 19:44:31
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	12 Apr 2021 17:56:52

US3012171

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:47:42

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	15 Apr 2021 16:35:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 19:44:33
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	12 Apr 2021 17:56:52

US3012171

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:47:42

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	15 Apr 2021 16:35:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 22:47:00
User entered '0' reason for change: Data Entry Error	Jennifer Leyva (b) (4)	13 Apr 2021 21:20:11
User entered '1' reason for change: Data Entry Error	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 18:01:44
User entered '0'		12 Apr 2021 17:56:52

US3012171

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:47:42

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	15 Apr 2021 16:35:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 22:47:02
User closed query 'Per source, Other Action Taken for this SAE, is recorded as, ConMed. Please verify and update EDC accordingly.' (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 22:46:58
Query 'Per source, Other Action Taken for this SAE, is recorded as, ConMed. Please verify and update EDC accordingly.' answered with 'Updated' (Site from CRA).	Jennifer Leyva (b) (4)	13 Apr 2021 21:21:06
	(b) (4)	
User entered '1' reason for change: Data Entry Error	Jennifer Leyva (b) (4)	13 Apr 2021 21:20:11
	(b) (4)	
User opened query 'Per source, Other Action Taken for this SAE, is recorded as, ConMed. Please verify and update EDC accordingly.' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 19:45:01
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Apr 2021 18:01:44
User entered '1'		12 Apr 2021 17:56:52

US3012171

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:47:42

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	15 Apr 2021 16:35:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 19:45:03
User entered '0'	(b) (4), (b) (6)	12 Apr 2021 17:56:52

US3012171

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:47:42

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	15 Apr 2021 16:35:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 19:45:05
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	12 Apr 2021 17:56:52

US3012171

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:47:42

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	15 Apr 2021 16:35:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 19:45:07
User entered empty.	(b) (4), (b) (6)	12 Apr 2021 17:56:52

US3012171

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:47:42

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	15 Apr 2021 16:35:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 19:45:08
User entered 'This dx was listed on the hospital medical records along with UTI and leukocytosis.'	(b) (4), (b) (6)	12 Apr 2021 18:01:44
reason for change: Data Entry Error		
User entered empty.		12 Apr 2021 17:56:52

US3012171

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:47:42

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Apr 2021 18:02:39
User entered '0'	System	12 Apr 2021 17:56:52

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:47:42

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	12 Apr 2021 17:56:52

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:47:42

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	12 Apr 2021 18:02:18

US3012171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 14:47:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:53:20
Query 'Per source, the following ConMeds are recorded in the ConMed Log, but not entered in EDC: Docusate (Colace), Acetaminophen-Hydrocodone, Glipizide, Metformin, Novolog (insulin), and Advil. Please verify with source and update EDC accordingly.' canceled (Site from CRA).	(b) (4), (b) (6)	15 Apr 2021 21:06:28
User opened query 'Per source, the following ConMeds are recorded in the ConMed Log, but not entered in EDC: Docusate (Colace), Acetaminophen-Hydrocodone, Glipizide, Metformin, Novolog (insulin), and Advil. Please verify with source and update EDC accordingly.' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 20:02:11
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:45:34
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) Pamela Fidler (b) (4)	10 Nov 2020 23:41:50
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	19 Aug 2020 15:32:32

US3012171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:47:42

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:06:34
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:45:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY, PRODUCT: BORON;CHROMIUM;COPPER;GERMANIUM;IO DINE;MANGANESE;MOLYBDENUM;SELENIU M;SILICON;SITOSTEROL;VANADIUM;VITAMI N D NOS;ZINC, PRODUCTSYNONYM: SUPER BETA PROSTATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 23:43:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 23:43:41
Data point term sent to Coder	System	10 Nov 2020 23:42:54
User entered 'Super Beta Prostate'	Pamela Fidler (b) (4)	10 Nov 2020 23:42:47

US3012171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:47:42

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:06:34
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:45:51
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'No (N)'	(b) (4) Pamela Fidler (b) (4)	10 Nov 2020 23:42:47

US3012171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:47:42

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:06:34
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:45:54
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Nutritional Supplement'	(b) (4) Pamela Fidler (b) (4)	10 Nov 2020 23:42:47

US3012171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:47:42

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:06:34
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:45:57
User signature succeeded.	Laurence Chu (b) (4)	09 Apr 2021 20:42:01
Signature has been broken.	(b) (4)	
	Pamela Fidler (b) (4)	08 Apr 2021 19:35:30
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
	(b) (4)	
User entered 'I'	Pamela Fidler (b) (4)	10 Nov 2020 23:42:47

US3012171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:47:42

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:06:34
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:45:58
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'tablet (TABLET)'	(b) (4) Pamela Fidler (b) (4)	10 Nov 2020 23:42:47

US3012171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:47:42

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:06:34
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:46:00
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered empty.	(b) (4) Pamela Fidler (b) (4)	10 Nov 2020 23:42:47

US3012171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:47:42

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:06:34
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:46:01
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'twice daily (BID)'	(b) (4) Pamela Fidler (b) (4)	10 Nov 2020 23:42:47

US3012171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:47:42

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:06:34
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:46:03
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered empty.	(b) (4) Pamela Fidler (b) (4)	10 Nov 2020 23:42:47

US3012171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:47:42

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:06:34
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:46:05
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Oral (ORAL)'	(b) (4) Pamela Fidler (b) (4)	10 Nov 2020 23:42:47

US3012171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:47:42

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:06:34
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:46:07
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered empty.	(b) (4) Pamela Fidler (b) (4)	10 Nov 2020 23:42:47

US3012171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:47:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:06:34
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:46:09
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered '09 Oct 2020'	(b) (4) Pamela Fidler (b) (4)	10 Nov 2020 23:42:47

US3012171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:47:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:06:34
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:46:10
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered '0'	(b) (4) Pamela Fidler (b) (4)	10 Nov 2020 23:42:47

US3012171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:47:42

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:06:34
User signature succeeded.	Laurence Chu (b) (4)	15 Apr 2021 16:35:55
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:48:03
User closed query 'Per source, End Date of ConMed is recorded as, 18Mar2021. Please verify and update EDC accordingly.' (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 22:48:01
Query 'Per source, End Date of ConMed is recorded as, 18Mar2021. Please verify and update EDC accordingly.' answered with 'Updated' (Site from CRA).	Jennifer Leyva (b) (4)	13 Apr 2021 21:23:46
Signature has been broken.	Jennifer Leyva (b) (4)	13 Apr 2021 21:23:32
User entered 'No (N)' reason for change: New Information	Jennifer Leyva (b) (4)	13 Apr 2021 21:23:32
User opened query 'Per source, End Date of ConMed is recorded as, 18Mar2021. Please verify and update EDC accordingly.' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 19:46:40
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Yes (Y)'	Pamela Fidler (b) (4)	10 Nov 2020 23:42:47

US3012171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:47:42

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:06:34
User signature succeeded.	Laurence Chu (b) (4)	15 Apr 2021 16:35:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 22:48:05
Signature has been broken.	Jennifer Leyva (b) (4)	13 Apr 2021 21:23:32
User entered '18 Mar 2021' reason for change: New Information	(b) (4) Jennifer Leyva (b) (4)	13 Apr 2021 21:23:32
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered empty.	(b) (4) Pamela Fidler (b) (4)	10 Nov 2020 23:42:47

US3012171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:47:42

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:06:34
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:46:43
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'No (N)'	(b) (4) Pamela Fidler (b) (4)	10 Nov 2020 23:42:47

US3012171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:47:42

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:06:34
User entered '2'	System	10 Nov 2020 23:42:47

US3012171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:47:42

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:06:34
User entered '1'	System	10 Nov 2020 23:42:47

US3012171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:47:42

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:06:34
User entered '804 (804)'	System	10 Nov 2020 23:42:47

US3012171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:47:42

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:06:27
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:46:46
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Nov 2020 23:44:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Nov 2020 23:44:41
Data point term sent to Coder	System	10 Nov 2020 23:43:56
User entered 'Influenza Vaccine'	Pamela Fidler (b) (4)	10 Nov 2020 23:43:35

US3012171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:47:42

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:06:27
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:46:54
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Yes (Y)'	(b) (4) Pamela Fidler (b) (4)	10 Nov 2020 23:43:35

US3012171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:47:42

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:06:27
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:46:56
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Influenza Prevention'	(b) (4) Pamela Fidler (b) (4)	10 Nov 2020 23:43:35

US3012171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:47:42

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:06:27
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:46:58
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered '.5'	(b) (4) Pamela Fidler (b) (4)	10 Nov 2020 23:43:35

US3012171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:47:42

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:06:27
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:46:59
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'mL (mL)'	(b) (4) Pamela Fidler (b) (4)	10 Nov 2020 23:43:35

US3012171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:47:42

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:06:27
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:47:01
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered empty.	(b) (4) Pamela Fidler (b) (4)	10 Nov 2020 23:43:35

US3012171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:47:42

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:06:27
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:47:02
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'once (ONCE)'	(b) (4) Pamela Fidler (b) (4)	10 Nov 2020 23:43:35

US3012171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:47:42

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:06:27
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:47:25
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered empty.	(b) (4) Pamela Fidler (b) (4)	10 Nov 2020 23:43:35

US3012171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:47:42

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:06:27
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:47:28
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) Pamela Fidler (b) (4)	10 Nov 2020 23:43:35

US3012171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:47:42

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:06:27
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:47:30
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered empty.	(b) (4) Pamela Fidler (b) (4)	10 Nov 2020 23:43:35

US3012171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:47:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:06:27
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:47:42
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered '27 Oct 2020'	(b) (4) Pamela Fidler (b) (4)	10 Nov 2020 23:43:35

US3012171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:47:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:06:27
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:47:42
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered '0'	(b) (4) Pamela Fidler (b) (4)	10 Nov 2020 23:43:35

US3012171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:47:42

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:06:27
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:47:42
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'No (N)'	(b) (4) Pamela Fidler (b) (4)	10 Nov 2020 23:43:35

US3012171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:47:42

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:06:27
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:47:42
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered '27 Oct 2020'	(b) (4) Pamela Fidler (b) (4)	10 Nov 2020 23:43:35

US3012171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:47:42

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:06:27
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:47:42
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'No (N)'	(b) (4) Pamela Fidler (b) (4)	10 Nov 2020 23:43:35

US3012171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:47:42

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:06:27
User entered empty.	System	10 Nov 2020 23:43:35

US3012171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:47:42

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:06:27
User entered empty.	System	10 Nov 2020 23:43:35

US3012171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:47:42

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:06:27
User entered empty.	System	10 Nov 2020 23:43:35

US3012171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:47:42

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY, ATC: ALPHA-ADRENORECEPTOR ANTAGONISTS, PRODUCT: TAMSULOSIN HYDROCHLORIDE, PRODUCTSYNONYM: FLOMAX [TAMSULOSIN HYDROCHLORIDE] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	14 Apr 2021 11:20:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	14 Apr 2021 11:20:50
Data point term sent to Coder	System	14 Apr 2021 11:15:03
Query 'CDM-Coding: The trade name FLOMAX can be referred as multiple ingredients in the standard coding dictionary. Please enter the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. Thank you.	Coder Import (b) (4)	14 Apr 2021 11:14:07
' canceled (Site from System).		
User opened query 'CDM-Coding: The trade name FLOMAX can be referred as multiple ingredients in the standard coding dictionary. Please enter the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. Thank you.	Coder Import (b) (4)	14 Apr 2021 09:38:41
' (Site from System).		
Data point term sent to Coder	System	13 Apr 2021 21:25:53
Coding entries removed.	Jennifer Leyva (b) (4)	13 Apr 2021 21:24:53
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:57:13
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20

US3012171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:47:42

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY, ATC: ALPHA-ADRENORECEPTOR ANTAGONISTS, PRODUCT: TAMSULOSIN HYDROCHLORIDE, PRODUCTSYNONYM: FLOMAX [TAMSULOSIN HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 09:56:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 09:56:41
Data point term sent to Coder	System	15 Mar 2021 21:10:55
User entered 'Flomax'	Jennifer Leyva (b) (4) (b) (4)	15 Mar 2021 21:10:00

US3012171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:47:42

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:57:23
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'No (N)'	Jennifer Leyva (b) (4)	15 Mar 2021 21:10:00

US3012171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:47:42

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	15 Apr 2021 16:35:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 22:48:16
User closed query 'Per source, indication is recorded as, UTI. Please verify and update EDC accordingly.' (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 22:48:15
Query 'Per source, indication is recorded as, UTI. Please verify and update EDC accordingly.' answered with 'Updated' (Site from CRA).	Jennifer Leyva (b) (4)	13 Apr 2021 21:25:06
Signature has been broken.	(b) (4)	
	Jennifer Leyva (b) (4)	13 Apr 2021 21:24:53
User entered 'URINARY TRACT INFECTION (AE #1)' reason for change: Data Entry Error	Jennifer Leyva (b) (4)	13 Apr 2021 21:24:53
User opened query 'Per source, indication is recorded as, UTI. Please verify and update EDC accordingly.' (Site from CRA).	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 19:57:56
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:57:33
	(b) (4)	13 Apr 2021 19:57:25
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
	(b) (4)	
User entered 'Urinary Tract Infection, Bladder Infection (AE #1 and AE #2)'	Jennifer Leyva (b) (4)	15 Mar 2021 21:10:00
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:47:42

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:57:30
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered '0.4'	Jennifer Leyva (b) (4)	15 Mar 2021 21:10:00

US3012171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:47:42

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:58:08
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'mg (mg)'	Jennifer Leyva (b) (4)	15 Mar 2021 21:10:00

US3012171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:47:42

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:58:10
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered empty.	Jennifer Leyva (b) (4)	15 Mar 2021 21:10:00

US3012171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:47:42

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:58:12
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'once daily (QD)'	Jennifer Leyva (b) (4)	15 Mar 2021 21:10:00

US3012171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:47:42

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:58:14
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered empty.	Jennifer Leyva (b) (4)	15 Mar 2021 21:10:00

US3012171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:47:42

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:58:17
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Oral (ORAL)'	Jennifer Leyva (b) (4)	15 Mar 2021 21:10:00

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:47:42

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:58:20
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered empty.	Jennifer Leyva (b) (4)	15 Mar 2021 21:10:00

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:47:42

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:58:22
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered '12 Mar 2021'	Jennifer Leyva (b) (4)	15 Mar 2021 21:10:00

US3012171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:47:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:58:23
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered '0'	Jennifer Leyva (b) (4)	15 Mar 2021 21:10:00

US3012171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:47:42

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:58:25
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Yes (Y)'	Jennifer Leyva (b) (4)	15 Mar 2021 21:10:00

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:47:42

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:58:26
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered empty.	Jennifer Leyva (b) (4)	15 Mar 2021 21:10:00

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:47:42

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:58:28
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'No (N)'	Jennifer Leyva (b) (4)	15 Mar 2021 21:10:00

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:47:42

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Mar 2021 21:10:00

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:47:42

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Mar 2021 21:10:00

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:47:42

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Mar 2021 21:10:00

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:47:42

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:07:11
User signature succeeded.	Laurence Chu (b) (4)	15 Apr 2021 16:35:55
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS, PRODUCT: AMOXICILLIN;CLAVULANIC ACID - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Apr 2021 07:17:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Apr 2021 07:17:39
Data point term sent to Coder DataPoint Verified.	System (b) (4), (b) (6)	13 Apr 2021 21:26:54 13 Apr 2021 19:58:35
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	12 Apr 2021 18:04:46 12 Apr 2021 18:04:41
Coding entries removed.		12 Apr 2021 18:04:41
Signature has been broken.		12 Apr 2021 18:04:41
User entered 'amoxicillin clavulanate' reason for change: Data Entry Error		12 Apr 2021 18:04:41
User signature succeeded.	Laurence Chu (b) (4)	09 Apr 2021 20:42:01
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS, PRODUCT: AMPICILLIN;SULBACTAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Apr 2021 20:42:50

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:47:42

Name of Medication

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003. Data point term sent to Coder Coding entries removed.	Coder Import (b) (4) (b) (4) System Pamela Fidler (b) (4) (b) (4) (b) (4)	08 Apr 2021 20:42:50 08 Apr 2021 19:36:31 08 Apr 2021 19:35:58
Signature has been broken.	Pamela Fidler (b) (4) (b) (4)	08 Apr 2021 19:35:58
User entered 'Ampicillin Sulbactam' reason for change: Data Entry Error	Pamela Fidler (b) (4) (b) (4)	08 Apr 2021 19:35:58
User closed query 'Per DM CLR: Please note, the medication cannot be verified as entered. Please update the Medication Name to reflect the complete name (either trade or generic) of the medication rather than the drug classification. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6) (b) (4)	06 Apr 2021 12:39:29
Query 'Per DM CLR: Please note, the medication cannot be verified as entered. Please update the Medication Name to reflect the complete name (either trade or generic) of the medication rather than the drug classification. Update eCRF as appropriate.' answered with 'We are awaiting the patient to give us the exact name this was all they knew when we spoke will follow up' (Site from DM).	Pamela Fidler (b) (4) (b) (4)	29 Mar 2021 17:03:06
User opened query 'Per DM CLR: Please note, the medication cannot be verified as entered. Please update the Medication Name to reflect the complete name (either trade or generic) of the medication rather than the drug classification. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6) (b) (4)	29 Mar 2021 09:15:16
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 00:56:20
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, PRODUCT: ANTIBIOTICS - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	16 Mar 2021 08:54:00
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	16 Mar 2021 08:54:00

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

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[Name of Medication](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	15 Mar 2021 21:10:55
User entered 'Antibiotic'	Jennifer Leyva (b) (4)	15 Mar 2021 21:10:39
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:47:42

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:07:11
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:58:42
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'No (N)'	Jennifer Leyva (b) (4)	15 Mar 2021 21:10:39

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:47:42

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:07:11
User signature succeeded.	Laurence Chu (b) (4)	15 Apr 2021 16:35:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 22:48:25
User closed query 'Per source, indication is recorded as, UTI. Please verify and update EDC accordingly.' (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 22:48:24
Query 'Per source, indication is recorded as, UTI. Please verify and update EDC accordingly.' answered with 'Updated' (Site from CRA).	Jennifer Leyva (b) (4)	13 Apr 2021 21:26:21
User entered 'UTI (AE #1)' reason for change: Data Entry Error	Jennifer Leyva (b) (4)	13 Apr 2021 21:26:07
User opened query 'Per source, indication is recorded as, UTI. Please verify and update EDC accordingly.' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 19:59:04
Signature has been broken.	(b) (4), (b) (6)	12 Apr 2021 18:04:41
User entered 'UTI / BLADDER INFECTION (AE #1 AND AE #2 and ae#3)' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Apr 2021 18:04:41
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'UTI / Bladder Infection (AE #1 and AE #2)'	Jennifer Leyva (b) (4)	15 Mar 2021 21:10:39

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:47:42

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:07:11
User signature succeeded.	Laurence Chu (b) (4)	15 Apr 2021 16:35:55
User closed query 'Per CDM: Dose per administration is recorded as UN; However per CCGs page 53, if the dose is unknown, it should be recorded as "UNK". Please update accordingly. Thank you' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Apr 2021 16:10:10
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:59:06
User entered '875' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Apr 2021 18:04:41
Query 'Per CDM: Dose per administration is recorded as UN; However per CCGs page 53, if the dose is unknown, it should be recorded as "UNK". Please update accordingly. Thank you' answered with 'Updated' (Site from DM).	Pamela Fidler (b) (4)	12 Apr 2021 14:28:02
Signature has been broken.	Pamela Fidler (b) (4)	12 Apr 2021 14:27:48
User entered 'UNK' reason for change: Data Entry Error	Pamela Fidler (b) (4)	12 Apr 2021 14:27:48
User opened query 'Per CDM: Dose per administration is recorded as UN; However per CCGs page 53, if the dose is unknown, it should be recorded as "UNK". Please update accordingly. Thank you' (Site from DM).	(b) (4), (b) (6)	11 Apr 2021 05:50:53
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'UN'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	15 Mar 2021 21:10:39

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:47:42

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:07:11
User signature succeeded.	Laurence Chu (b) (4)	15 Apr 2021 16:35:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:59:08
User closed query 'Other, specify is provided, however Dose unit is not Other. Please correct.' (Site from System).	System	12 Apr 2021 18:05:05
User opened query 'Other, specify is provided, however Dose unit is not Other. Please correct.' (Site from System).	System	12 Apr 2021 18:04:41
Signature has been broken.	(b) (4), (b) (6)	12 Apr 2021 18:04:41
User entered 'mg (mg)' reason for change: Data Entry Error		12 Apr 2021 18:04:41
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Other (OTHER)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	15 Mar 2021 21:10:39

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:47:42

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:07:11
User signature succeeded.	Laurence Chu (b) (4)	15 Apr 2021 16:35:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:59:09
Signature has been broken.	(b) (4), (b) (6)	12 Apr 2021 18:05:05
User entered empty; reason for change Data Entry Error		12 Apr 2021 18:05:05
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'UN'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	15 Mar 2021 21:10:39

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:47:42

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:07:11
User signature succeeded.	Laurence Chu (b) (4)	15 Apr 2021 16:35:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:59:12
Signature has been broken.	(b) (4), (b) (6)	12 Apr 2021 18:04:41
User entered 'once daily (QD)' reason for change: Data Entry Error		12 Apr 2021 18:04:41
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'unknown (UNKNOWN)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	15 Mar 2021 21:10:39

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:47:42

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:07:11
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:59:13
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered empty.	Jennifer Leyva (b) (4)	15 Mar 2021 21:10:39

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:47:42

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:07:11
User signature succeeded.	Laurence Chu (b) (4)	15 Apr 2021 16:35:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:59:14
Signature has been broken.	(b) (4), (b) (6)	12 Apr 2021 18:04:41
User entered 'Oral (ORAL)' reason for change: Data Entry Error		12 Apr 2021 18:04:41
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Other (OTHER)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	15 Mar 2021 21:10:39

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:47:42

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:07:11
User signature succeeded.	Laurence Chu (b) (4)	15 Apr 2021 16:35:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:59:15
Signature has been broken.	(b) (4), (b) (6)	12 Apr 2021 18:04:41
User entered empty; reason for change Data Entry Error		12 Apr 2021 18:04:41
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'UN'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	15 Mar 2021 21:10:39

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:47:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:07:11
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:59:17
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered '12 Mar 2021'	Jennifer Leyva (b) (4)	15 Mar 2021 21:10:39

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:47:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:07:11
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:59:20
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered '0'	Jennifer Leyva (b) (4)	15 Mar 2021 21:10:39

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:47:42

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:07:11
User signature succeeded.	Laurence Chu (b) (4)	15 Apr 2021 16:35:55
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:48:30
User closed query 'Per source, End Date of ConMed is recorded as, 13Apr2021. Please verify and update EDC accordingly.' (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 22:48:29
Query 'Per source, End Date of ConMed is recorded as, 13Apr2021. Please verify and update EDC accordingly.' answered with 'Updated' (Site from CRA).	Jennifer Leyva (b) (4)	13 Apr 2021 21:26:36
Signature has been broken.	Jennifer Leyva (b) (4)	13 Apr 2021 21:26:07
User entered 'No (N)' reason for change: New Information	Jennifer Leyva (b) (4)	13 Apr 2021 21:26:07
User opened query 'Per source, End Date of ConMed is recorded as, 13Apr2021. Please verify and update EDC accordingly.' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 19:59:47
User closed query 'Per DM CLR: Please review and verify if this medication is ongoing as this is not the standard duration of treatment for this medication. Either update the Stop Date or provide explanation for continued use. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 13:56:59
Query 'Per DM CLR: Please review and verify if this medication is ongoing as this is not the standard duration of treatment for this medication. Either update the Stop Date or provide explanation for continued use. Update eCRF as appropriate.' answered with 'Still on going will update when we get the date ' (Site from DM).	Pamela Fidler (b) (4)	29 Mar 2021 17:03:28
User opened query 'Per DM CLR: Please review and verify if this medication is ongoing as this is not the standard duration of treatment for this medication. Either update the Stop Date or provide explanation for continued use. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 09:15:25
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'Yes (Y)'	Jennifer Leyva (b) (4)	15 Mar 2021 21:10:39

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:47:42

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:07:11
User signature succeeded.	Laurence Chu (b) (4)	15 Apr 2021 16:35:55
DataPoint Verified.	(b) (4)	14 Apr 2021 22:48:31
DataPoint Un-verified.	(b) (4), (b) (6)	14 Apr 2021 22:48:31
Signature has been broken.	Jennifer Leyva (b) (4)	13 Apr 2021 21:26:07
User entered '13 Apr 2021' reason for change: New Information	(b) (4)	13 Apr 2021 21:26:07
DataPoint Verified.	Jennifer Leyva (b) (4)	13 Apr 2021 21:26:07
User signature succeeded.	(b) (4)	13 Apr 2021 19:59:49
User entered empty.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
	(b) (4)	15 Mar 2021 21:10:39
	Jennifer Leyva (b) (4)	
	(b) (4)	

US3012171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:47:42

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:07:11
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:59:51
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'No (N)'	Jennifer Leyva (b) (4)	15 Mar 2021 21:10:39

US3012171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:47:42

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:07:11
User entered '1'	System	12 Apr 2021 18:04:41
User entered empty.	System	15 Mar 2021 21:10:39

US3012171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:47:42

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:07:11
User entered '1'	System	12 Apr 2021 18:04:41
User entered empty.	System	15 Mar 2021 21:10:39

US3012171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:47:42

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:07:11
User entered '804 (804)'	System	12 Apr 2021 18:04:41
User entered empty.	System	15 Mar 2021 21:10:39

US3012171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:47:42

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:07:39
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: SOFTENERS, EMOLLIENTS, PRODUCT: DOCUSATE SODIUM, PRODUCTSYNONYM: COLACE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Apr 2021 12:52:09
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	(b) (4)	20 Apr 2021 12:52:09
Data point term sent to Coder	System	16 Apr 2021 19:54:03
Coding entries removed.	Pamela Fidler (b) (4)	16 Apr 2021 19:53:41
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:00:10
User signature succeeded.	Laurence Chu (b) (4)	15 Apr 2021 16:35:55
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: SOFTENERS, EMOLLIENTS, PRODUCT: DOCUSATE - version WHODrug-Global-B3\\202003.	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Apr 2021 10:13:53
Data point term sent to Coder	System	13 Apr 2021 21:37:01
User entered 'Docusate (Colace)'	Pamela Fidler (b) (4)	13 Apr 2021 21:36:43
DataPoint activated with code reason code Data required.	Pamela Fidler (b) (4)	13 Apr 2021 21:35:47
DataPoint inactivated with code reason code Data not required.	Pamela Fidler (b) (4)	08 Apr 2021 19:35:30

US3012171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:47:42

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:07:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:00:15
User signature succeeded.	Laurence Chu (b) (4)	15 Apr 2021 16:35:55
User entered 'No (N)'	(b) (4) Pamela Fidler (b) (4)	13 Apr 2021 21:36:43
DataPoint activated with code reason code Data required.	Pamela Fidler (b) (4)	13 Apr 2021 21:35:47
DataPoint inactivated with code reason code Data not required.	Pamela Fidler (b) (4)	08 Apr 2021 19:35:30

US3012171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:47:42

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:07:39
User signature succeeded.	Laurence Chu (b) (4)	16 Apr 2021 22:33:31
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:14:54
User closed query 'Per source, indication for ConMed is recorded as, Epididymitis. Please verify and update EDC accordingly.' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 21:14:39
Query 'Per source, indication for ConMed is recorded as, Epididymitis. Please verify and update EDC accordingly.' answered with 'Updated' (Site from CRA).	Pamela Fidler (b) (4)	16 Apr 2021 19:53:56
Signature has been broken.	Pamela Fidler (b) (4)	16 Apr 2021 19:53:41
User entered 'Epididymitis' reason for change: Data Entry Error	Pamela Fidler (b) (4)	16 Apr 2021 19:53:41
User opened query 'Per source, indication for ConMed is recorded as, Epididymitis. Please verify and update EDC accordingly.' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 19:42:35
User signature succeeded.	Laurence Chu (b) (4)	15 Apr 2021 16:35:55
User entered 'Constipation'	Pamela Fidler (b) (4)	13 Apr 2021 21:36:43
DataPoint activated with code reason code Data required.	Pamela Fidler (b) (4)	13 Apr 2021 21:35:47
DataPoint inactivated with code reason code Data not required.	Pamela Fidler (b) (4)	08 Apr 2021 19:35:30

US3012171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:47:42

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:07:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:01:05
User signature succeeded.	Laurence Chu (b) (4)	15 Apr 2021 16:35:55
User entered '100'	(b) (4) Pamela Fidler (b) (4)	13 Apr 2021 21:36:43
DataPoint activated with code reason code Data required.	Pamela Fidler (b) (4)	13 Apr 2021 21:35:47
DataPoint inactivated with code reason code Data not required.	Pamela Fidler (b) (4)	08 Apr 2021 19:35:30

US3012171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:47:42

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:07:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:01:07
User signature succeeded.	Laurence Chu (b) (4)	15 Apr 2021 16:35:55
User entered 'mg (mg)'	(b) (4) Pamela Fidler (b) (4)	13 Apr 2021 21:36:43
DataPoint activated with code reason code Data required.	Pamela Fidler (b) (4)	13 Apr 2021 21:35:47
DataPoint inactivated with code reason code Data not required.	Pamela Fidler (b) (4)	08 Apr 2021 19:35:30

US3012171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:47:42

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:07:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:01:08
User signature succeeded.	Laurence Chu (b) (4)	15 Apr 2021 16:35:55
User entered empty.	(b) (4) Pamela Fidler (b) (4)	13 Apr 2021 21:36:43
DataPoint activated with code reason code Data required.	Pamela Fidler (b) (4)	13 Apr 2021 21:35:47
DataPoint inactivated with code reason code Data not required.	Pamela Fidler (b) (4)	08 Apr 2021 19:35:30

US3012171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:47:42

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:07:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:01:10
User signature succeeded.	Laurence Chu (b) (4)	15 Apr 2021 16:35:55
User entered 'as needed (PRN)'	(b) (4) Pamela Fidler (b) (4)	13 Apr 2021 21:36:43
DataPoint activated with code reason code Data required.	Pamela Fidler (b) (4)	13 Apr 2021 21:35:47
DataPoint inactivated with code reason code Data not required.	Pamela Fidler (b) (4)	08 Apr 2021 19:35:30

US3012171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:47:42

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:07:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:01:13
User signature succeeded.	Laurence Chu (b) (4)	15 Apr 2021 16:35:55
User entered empty.	(b) (4) Pamela Fidler (b) (4)	13 Apr 2021 21:36:43
DataPoint activated with code reason code Data required.	Pamela Fidler (b) (4)	13 Apr 2021 21:35:47
DataPoint inactivated with code reason code Data not required.	Pamela Fidler (b) (4)	08 Apr 2021 19:35:30

US3012171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:47:42

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:07:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:01:14
User signature succeeded.	Laurence Chu (b) (4)	15 Apr 2021 16:35:55
User entered 'Oral (ORAL)'	(b) (4) Pamela Fidler (b) (4)	13 Apr 2021 21:36:43
DataPoint activated with code reason code Data required.	Pamela Fidler (b) (4)	13 Apr 2021 21:35:47
DataPoint inactivated with code reason code Data not required.	Pamela Fidler (b) (4)	08 Apr 2021 19:35:30

US3012171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:47:42

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:07:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:01:16
User signature succeeded.	Laurence Chu (b) (4)	15 Apr 2021 16:35:55
User entered empty.	(b) (4) Pamela Fidler (b) (4)	13 Apr 2021 21:36:43
DataPoint activated with code reason code Data required.	Pamela Fidler (b) (4)	13 Apr 2021 21:35:47
DataPoint inactivated with code reason code Data not required.	Pamela Fidler (b) (4)	08 Apr 2021 19:35:30

US3012171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:47:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:07:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:01:17
User signature succeeded.	Laurence Chu (b) (4)	15 Apr 2021 16:35:55
User entered '12 Mar 2021'	(b) (4) Pamela Fidler (b) (4)	13 Apr 2021 21:36:43
DataPoint activated with code reason code Data required.	Pamela Fidler (b) (4)	13 Apr 2021 21:35:47
DataPoint inactivated with code reason code Data not required.	Pamela Fidler (b) (4)	08 Apr 2021 19:35:30

US3012171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:47:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:07:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:01:18
User signature succeeded.	Laurence Chu (b) (4)	15 Apr 2021 16:35:55
User entered '0'	(b) (4) Pamela Fidler (b) (4)	13 Apr 2021 21:36:43
DataPoint activated with code reason code Data required.	Pamela Fidler (b) (4)	13 Apr 2021 21:35:47
DataPoint inactivated with code reason code Data not required.	Pamela Fidler (b) (4)	08 Apr 2021 19:35:30

US3012171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:47:42

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:07:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:01:20
User signature succeeded.	Laurence Chu (b) (4)	15 Apr 2021 16:35:55
User entered 'No (N)'	(b) (4) Pamela Fidler (b) (4)	13 Apr 2021 21:36:43
DataPoint activated with code reason code Data required.	Pamela Fidler (b) (4)	13 Apr 2021 21:35:47
DataPoint inactivated with code reason code Data not required.	Pamela Fidler (b) (4)	08 Apr 2021 19:35:30

US3012171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:47:42

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:07:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:01:21
User signature succeeded.	Laurence Chu (b) (4)	15 Apr 2021 16:35:55
User entered '21 Mar 2021'	(b) (4) Pamela Fidler (b) (4)	13 Apr 2021 21:36:43
DataPoint activated with code reason code Data required.	Pamela Fidler (b) (4)	13 Apr 2021 21:35:47
DataPoint inactivated with code reason code Data not required.	Pamela Fidler (b) (4)	08 Apr 2021 19:35:30

US3012171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:47:42

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:07:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:01:23
User signature succeeded.	Laurence Chu (b) (4)	15 Apr 2021 16:35:55
User entered 'No (N)'	(b) (4) Pamela Fidler (b) (4)	13 Apr 2021 21:36:43
DataPoint activated with code reason code Data required.	Pamela Fidler (b) (4)	13 Apr 2021 21:35:47
DataPoint inactivated with code reason code Data not required.	Pamela Fidler (b) (4)	08 Apr 2021 19:35:30

US3012171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:47:42

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:07:39
User entered empty.	System	13 Apr 2021 21:36:43
DataPoint activated with code reason code Data required.	Pamela Fidler (b) (4)	13 Apr 2021 21:35:47
DataPoint inactivated with code reason code Data not required.	Pamela Fidler (b) (4)	08 Apr 2021 19:35:30

US3012171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:47:42

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:07:39
User entered empty.	System	13 Apr 2021 21:36:43
DataPoint activated with code reason code Data required.	Pamela Fidler (b) (4)	13 Apr 2021 21:35:47
DataPoint inactivated with code reason code Data not required.	Pamela Fidler (b) (4)	08 Apr 2021 19:35:30

US3012171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:47:42

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:07:39
User entered empty.	System	13 Apr 2021 21:36:43
DataPoint activated with code reason code Data required.	Pamela Fidler (b) (4)	13 Apr 2021 21:35:47
DataPoint inactivated with code reason code Data not required.	Pamela Fidler (b) (4)	08 Apr 2021 19:35:30

US3012171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:47:42

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:02
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:01:32
User signature succeeded.	Laurence Chu (b) (4)	15 Apr 2021 16:35:55
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: HYDROCODONE;PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN;HYDROCODONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 06:43:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 06:43:45
Data point term sent to Coder	System	13 Apr 2021 21:39:03
User entered 'Acetaminophen-Hydrocodone'	Pamela Fidler (b) (4)	13 Apr 2021 21:38:30

US3012171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:47:42

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:02
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:01:41
User signature succeeded.	Laurence Chu (b) (4)	15 Apr 2021 16:35:55
User entered 'No (N)'	(b) (4) Pamela Fidler (b) (4)	13 Apr 2021 21:38:30

US3012171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:47:42

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:02
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:01:37
User signature succeeded.	Laurence Chu (b) (4)	15 Apr 2021 16:35:55
User entered 'Pain Due to UTI, Leukocytosis'	(b) (4) Pamela Fidler (b) (4)	13 Apr 2021 21:38:30

US3012171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:47:42

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:02
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:01:43
User signature succeeded.	Laurence Chu (b) (4)	15 Apr 2021 16:35:55
User entered '5/325'	(b) (4) Pamela Fidler (b) (4)	13 Apr 2021 21:38:30

US3012171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:47:42

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:02
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:01:45
User signature succeeded.	Laurence Chu (b) (4)	15 Apr 2021 16:35:55
User entered 'mg (mg)'	(b) (4) Pamela Fidler (b) (4)	13 Apr 2021 21:38:30

US3012171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:47:42

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:02
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:01:46
User signature succeeded.	Laurence Chu (b) (4)	15 Apr 2021 16:35:55
User entered empty.	(b) (4) Pamela Fidler (b) (4)	13 Apr 2021 21:38:30

US3012171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:47:42

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:02
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:01:49
User signature succeeded.	Laurence Chu (b) (4)	15 Apr 2021 16:35:55
User entered 'four times daily (QID)'	(b) (4) Pamela Fidler (b) (4)	13 Apr 2021 21:38:30

US3012171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:47:42

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:02
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:01:53
User signature succeeded.	Laurence Chu (b) (4)	15 Apr 2021 16:35:55
User entered empty.	(b) (4) Pamela Fidler (b) (4)	13 Apr 2021 21:38:30

US3012171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:47:42

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:02
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:01:54
User signature succeeded.	Laurence Chu (b) (4)	15 Apr 2021 16:35:55
User entered 'Oral (ORAL)'	(b) (4) Pamela Fidler (b) (4)	13 Apr 2021 21:38:30

US3012171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:47:42

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:02
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:01:56
User signature succeeded.	Laurence Chu (b) (4)	15 Apr 2021 16:35:55
User entered empty.	(b) (4) Pamela Fidler (b) (4)	13 Apr 2021 21:38:30

US3012171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:47:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:02
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:01:58
User signature succeeded.	Laurence Chu (b) (4)	15 Apr 2021 16:35:55
User entered '12 Mar 2021'	(b) (4) Pamela Fidler (b) (4)	13 Apr 2021 21:38:30

US3012171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:47:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:02
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:02:00
User signature succeeded.	Laurence Chu (b) (4)	15 Apr 2021 16:35:55
User entered '0'	(b) (4) Pamela Fidler (b) (4)	13 Apr 2021 21:38:30

US3012171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:47:42

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:02
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:02:02
User signature succeeded.	Laurence Chu (b) (4)	15 Apr 2021 16:35:55
User entered 'No (N)'	(b) (4) Pamela Fidler (b) (4)	13 Apr 2021 21:38:30

US3012171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:47:42

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:02
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:02:06
User signature succeeded.	Laurence Chu (b) (4)	15 Apr 2021 16:35:55
User entered '21 Mar 2021'	(b) (4) Pamela Fidler (b) (4)	13 Apr 2021 21:38:30

US3012171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:47:42

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:02
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:02:08
User signature succeeded.	Laurence Chu (b) (4)	15 Apr 2021 16:35:55
User entered 'No (N)'	(b) (4) Pamela Fidler (b) (4)	13 Apr 2021 21:38:30

US3012171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:47:42

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:02
User entered '4'	System	13 Apr 2021 21:38:30

US3012171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:47:42

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:02
User entered '1'	System	13 Apr 2021 21:38:30

US3012171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:47:42

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:02
User entered '804 (804)'	System	13 Apr 2021 21:38:30

US3012171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:47:42

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:02:21
User signature succeeded.	Laurence Chu (b) (4)	15 Apr 2021 16:35:55
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: SULFONYLUREAS, PRODUCT: GLIPIZIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Apr 2021 21:40:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Apr 2021 21:40:39
Data point term sent to Coder	System	13 Apr 2021 21:40:04
User entered 'Glipizide'	Pamela Fidler (b) (4)	13 Apr 2021 21:39:24

US3012171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:47:42

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:02:24
User signature succeeded.	Laurence Chu (b) (4)	15 Apr 2021 16:35:55
User entered 'No (N)'	(b) (4) Pamela Fidler (b) (4)	13 Apr 2021 21:39:24

US3012171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:47:42

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:03:45
User signature succeeded.	Laurence Chu (b) (4)	15 Apr 2021 16:35:55
User entered 'T2DM'	Pamela Fidler (b) (4)	13 Apr 2021 21:39:24

US3012171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:47:42

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:04:08
User signature succeeded.	Laurence Chu (b) (4)	15 Apr 2021 16:35:55
User entered '10'	(b) (4) Pamela Fidler (b) (4)	13 Apr 2021 21:39:24

US3012171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:47:42

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:04:10
User signature succeeded.	Laurence Chu (b) (4)	15 Apr 2021 16:35:55
User entered 'mg (mg)'	(b) (4) Pamela Fidler (b) (4)	13 Apr 2021 21:39:24

US3012171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:47:42

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:04:12
User signature succeeded.	Laurence Chu (b) (4)	15 Apr 2021 16:35:55
User entered empty.	(b) (4) Pamela Fidler (b) (4)	13 Apr 2021 21:39:24

US3012171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:47:42

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:04:14
User signature succeeded.	Laurence Chu (b) (4)	15 Apr 2021 16:35:55
User entered 'twice daily (BID)'	(b) (4) Pamela Fidler (b) (4)	13 Apr 2021 21:39:24

US3012171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:47:42

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:04:16
User signature succeeded.	Laurence Chu (b) (4)	15 Apr 2021 16:35:55
User entered empty.	(b) (4) Pamela Fidler (b) (4)	13 Apr 2021 21:39:24

US3012171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:47:42

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:04:18
User signature succeeded.	Laurence Chu (b) (4)	15 Apr 2021 16:35:55
User entered 'Oral (ORAL)'	(b) (4) Pamela Fidler (b) (4)	13 Apr 2021 21:39:24

US3012171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:47:42

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:04:20
User signature succeeded.	Laurence Chu (b) (4)	15 Apr 2021 16:35:55
User entered empty.	(b) (4) Pamela Fidler (b) (4)	13 Apr 2021 21:39:24

US3012171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:47:42

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:04:34
User signature succeeded.	Laurence Chu (b) (4)	15 Apr 2021 16:35:55
User entered '12 Mar 2021'	(b) (4) Pamela Fidler (b) (4)	13 Apr 2021 21:39:24

US3012171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:47:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:04:30
User signature succeeded.	Laurence Chu (b) (4)	15 Apr 2021 16:35:55
User entered '0'	Pamela Fidler (b) (4)	13 Apr 2021 21:39:24

US3012171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:47:42

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:04:23
User signature succeeded.	Laurence Chu (b) (4)	15 Apr 2021 16:35:55
User entered 'Yes (Y)'	(b) (4) Pamela Fidler (b) (4)	13 Apr 2021 21:39:24

US3012171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:47:42

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:04:25
User signature succeeded.	Laurence Chu (b) (4)	15 Apr 2021 16:35:55
User entered empty.	(b) (4) Pamela Fidler (b) (4)	13 Apr 2021 21:39:24

US3012171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:47:42

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:04:28
User signature succeeded.	Laurence Chu (b) (4)	15 Apr 2021 16:35:55
User entered 'No (N)'	(b) (4) Pamela Fidler (b) (4)	13 Apr 2021 21:39:24

US3012171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:47:42

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	13 Apr 2021 21:39:24

US3012171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:47:42

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Apr 2021 21:39:24

US3012171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:47:42

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Apr 2021 21:39:24

US3012171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:47:42

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:04:38
User signature succeeded.	Laurence Chu (b) (4)	15 Apr 2021 16:35:55
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: BIGUANIDES, PRODUCT: METFORMIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Apr 2021 21:40:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Apr 2021 21:40:40
Data point term sent to Coder	System	13 Apr 2021 21:40:04
User entered 'Metformin'	Pamela Fidler (b) (4)	13 Apr 2021 21:39:52

US3012171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:47:42

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:04:40
User signature succeeded.	Laurence Chu (b) (4)	15 Apr 2021 16:35:55
User entered 'No (N)'	(b) (4) Pamela Fidler (b) (4)	13 Apr 2021 21:39:52

US3012171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:47:42

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:04:43
User signature succeeded.	Laurence Chu (b) (4)	15 Apr 2021 16:35:55
User entered 'T2DM'	Pamela Fidler (b) (4)	13 Apr 2021 21:39:52

US3012171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:47:42

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:04:46
User signature succeeded.	Laurence Chu (b) (4)	15 Apr 2021 16:35:55
User entered '500'	(b) (4) Pamela Fidler (b) (4)	13 Apr 2021 21:39:52

US3012171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:47:42

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:04:48
User signature succeeded.	Laurence Chu (b) (4)	15 Apr 2021 16:35:55
User entered 'mg (mg)'	(b) (4) Pamela Fidler (b) (4)	13 Apr 2021 21:39:52

US3012171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:47:42

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:04:49
User signature succeeded.	Laurence Chu (b) (4)	15 Apr 2021 16:35:55
User entered empty.	(b) (4) Pamela Fidler (b) (4)	13 Apr 2021 21:39:52

US3012171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:47:42

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:04:52
User signature succeeded.	Laurence Chu (b) (4)	15 Apr 2021 16:35:55
User entered 'twice daily (BID)'	(b) (4) Pamela Fidler (b) (4)	13 Apr 2021 21:39:52

US3012171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:47:42

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:04:53
User signature succeeded.	Laurence Chu (b) (4)	15 Apr 2021 16:35:55
User entered empty.	(b) (4) Pamela Fidler (b) (4)	13 Apr 2021 21:39:52

US3012171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:47:42

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:04:57
User signature succeeded.	Laurence Chu (b) (4)	15 Apr 2021 16:35:55
User entered 'Oral (ORAL)'	(b) (4) Pamela Fidler (b) (4)	13 Apr 2021 21:39:52

US3012171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:47:42

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:04:59
User signature succeeded.	Laurence Chu (b) (4)	15 Apr 2021 16:35:55
User entered empty.	(b) (4) Pamela Fidler (b) (4)	13 Apr 2021 21:39:52

US3012171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:47:42

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:05:01
User signature succeeded.	Laurence Chu (b) (4)	15 Apr 2021 16:35:55
User entered '12 Mar 2021'	(b) (4) Pamela Fidler (b) (4)	13 Apr 2021 21:39:52

US3012171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:47:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:05:03
User signature succeeded.	Laurence Chu (b) (4)	15 Apr 2021 16:35:55
User entered '0'	(b) (4) Pamela Fidler (b) (4)	13 Apr 2021 21:39:52

US3012171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:47:42

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:05:05
User signature succeeded.	Laurence Chu (b) (4)	15 Apr 2021 16:35:55
User entered 'Yes (Y)'	(b) (4) Pamela Fidler (b) (4)	13 Apr 2021 21:39:52

US3012171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:47:42

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:05:06
User signature succeeded.	Laurence Chu (b) (4)	15 Apr 2021 16:35:55
User entered empty.	(b) (4) Pamela Fidler (b) (4)	13 Apr 2021 21:39:52

US3012171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:47:42

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:05:08
User signature succeeded.	Laurence Chu (b) (4)	15 Apr 2021 16:35:55
User entered 'No (N)'	(b) (4) Pamela Fidler (b) (4)	13 Apr 2021 21:39:52

US3012171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:47:42

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	13 Apr 2021 21:39:52

US3012171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:47:42

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Apr 2021 21:39:52

US3012171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:47:42

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Apr 2021 21:39:52

US3012171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:47:42

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:21
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:05:13
User signature succeeded.	Laurence Chu (b) (4)	15 Apr 2021 16:35:55
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, FAST-ACTING, PRODUCT: INSULIN ASPART, PRODUCTSYNONYM: NOVOLOG - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Apr 2021 08:55:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Apr 2021 08:55:41
Data point term sent to Coder	System	13 Apr 2021 21:41:05
User entered 'Novolog (insulin)'	Pamela Fidler (b) (4)	13 Apr 2021 21:40:54

US3012171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:47:42

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:21
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:05:18
User signature succeeded.	Laurence Chu (b) (4)	15 Apr 2021 16:35:55
User entered 'No (N)'	(b) (4) Pamela Fidler (b) (4)	13 Apr 2021 21:40:54

US3012171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:47:42

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:21
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:05:22
User signature succeeded.	Laurence Chu (b) (4)	15 Apr 2021 16:35:55
User entered 'T2DM'	(b) (4) Pamela Fidler (b) (4)	13 Apr 2021 21:40:54

US3012171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:47:42

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:21
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:05:24
User signature succeeded.	Laurence Chu (b) (4)	15 Apr 2021 16:35:55
User entered 'Low Dose Sliding Scale'	(b) (4) Pamela Fidler (b) (4)	13 Apr 2021 21:40:54

US3012171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:47:42

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:21
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:05:26
User signature succeeded.	Laurence Chu (b) (4)	15 Apr 2021 16:35:55
User entered 'Other (OTHER)'	(b) (4) Pamela Fidler (b) (4)	13 Apr 2021 21:40:54

US3012171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:47:42

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:21
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:05:28
User signature succeeded.	Laurence Chu (b) (4)	15 Apr 2021 16:35:55
User entered 'Low Dose Sliding Scale'	(b) (4) Pamela Fidler (b) (4)	13 Apr 2021 21:40:54

US3012171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:47:42

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:21
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:05:35
User signature succeeded.	Laurence Chu (b) (4)	15 Apr 2021 16:35:55
User entered 'once daily (QD)'	(b) (4) Pamela Fidler (b) (4)	13 Apr 2021 21:40:54

US3012171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:47:42

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:21
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:05:45
User signature succeeded.	Laurence Chu (b) (4)	15 Apr 2021 16:35:55
User entered empty.	(b) (4) Pamela Fidler (b) (4)	13 Apr 2021 21:40:54

US3012171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:47:42

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:21
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:05:47
User signature succeeded.	Laurence Chu (b) (4)	15 Apr 2021 16:35:55
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) Pamela Fidler (b) (4)	13 Apr 2021 21:40:54

US3012171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:47:42

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:21
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:05:51
User signature succeeded.	Laurence Chu (b) (4)	15 Apr 2021 16:35:55
User entered empty.	(b) (4) Pamela Fidler (b) (4)	13 Apr 2021 21:40:54

US3012171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:47:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:21
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:05:49
User signature succeeded.	Laurence Chu (b) (4)	15 Apr 2021 16:35:55
User entered '12 Mar 2021'	(b) (4) Pamela Fidler (b) (4)	13 Apr 2021 21:40:54

US3012171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:47:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:21
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:05:54
User signature succeeded.	Laurence Chu (b) (4)	15 Apr 2021 16:35:55
User entered '0'	(b) (4) Pamela Fidler (b) (4)	13 Apr 2021 21:40:54

US3012171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:47:42

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:21
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:05:56
User signature succeeded.	Laurence Chu (b) (4)	15 Apr 2021 16:35:55
User entered 'No (N)'	(b) (4) Pamela Fidler (b) (4)	13 Apr 2021 21:40:54

US3012171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:47:42

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:21
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:05:58
User signature succeeded.	Laurence Chu (b) (4)	15 Apr 2021 16:35:55
User entered '16 Mar 2021'	(b) (4) Pamela Fidler (b) (4)	13 Apr 2021 21:40:54

US3012171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:47:42

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:21
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:06:00
User signature succeeded.	Laurence Chu (b) (4)	15 Apr 2021 16:35:55
User entered 'No (N)'	(b) (4) Pamela Fidler (b) (4)	13 Apr 2021 21:40:54

US3012171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:47:42

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:21
User entered '1'	System	13 Apr 2021 21:40:54

US3012171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:47:42

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:21
User entered '1'	System	13 Apr 2021 21:40:54

US3012171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:47:42

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:08:21
User entered '804 (804)'	System	13 Apr 2021 21:40:54

US3012171

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 14:47:42

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 20:06:27
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'No (N)'	Jennifer Leyva (b) (4)	19 Aug 2020 15:32:38

US3012171

Folder: SAE USA-US006-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:42

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:45:28
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:04:08
User entered 'USA-US006-2021-MRNA-1273-P301000007'	System	16 Mar 2021 14:52:20

US3012171

Folder: SAE USA-US006-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:42

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:45:28
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 15:04:08
User entered 'Yes (Y)'	System	16 Mar 2021 14:52:20

US3012171

Folder: SAE USA-US006-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:42

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:45:28
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:04:08
User entered 'No (N)'	System	16 Mar 2021 14:52:20

US3012171

Folder: SAE USA-US006-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:42

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:45:28
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:04:08
User entered 'No (N)'	System	16 Mar 2021 14:52:20

US3012171

Folder: SAE USA-US006-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:42

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:45:28
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:04:08
User entered 'Yes (Y)'	System	16 Mar 2021 14:52:20

US3012171

Folder: SAE USA-US006-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:42

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:45:28
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:04:08
User entered 'No (N)'	System	16 Mar 2021 14:52:20

US3012171

Folder: SAE USA-US006-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:42

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:45:28
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:04:08
User entered 'No (N)'	System	16 Mar 2021 14:52:20

US3012171

Folder: SAE USA-US006-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:42

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:45:28
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:04:08
User entered 'No (N)'	System	16 Mar 2021 14:52:20

US3012171

Folder: SAE USA-US006-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:42

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:45:28
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:04:08
User entered 'Laurence'	System	16 Mar 2021 14:52:20

US3012171

Folder: SAE USA-US006-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:42

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:45:28
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:04:08
User entered 'Chu'	System	16 Mar 2021 14:52:20

US3012171

Folder: SAE USA-US006-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:42

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:45:28
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:04:08
User entered '3100 Red River Street'	System	16 Mar 2021 14:52:20

US3012171

Folder: SAE USA-US006-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:42

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:45:28
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:04:08
User entered 'Austin'	System	16 Mar 2021 14:52:20

US3012171

Folder: SAE USA-US006-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:42

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:45:28
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:04:08
User entered 'TX'	System	16 Mar 2021 14:52:20

US3012171

Folder: SAE USA-US006-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:42

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:45:28
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:04:08
User entered '78705'	System	16 Mar 2021 14:52:20

US3012171

Folder: SAE USA-US006-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:42

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:45:28
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:04:08
User entered 'US'	System	16 Mar 2021 14:53:19

US3012171

Folder: SAE USA-US006-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:42

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	14 Apr 2021 12:53:51
User entered '5'	System	13 Apr 2021 17:29:23
User entered '4'	System	09 Apr 2021 13:39:32
User entered '3'	System	29 Mar 2021 13:27:44
User entered '2'	System	25 Mar 2021 14:42:42
User entered '1'	System	16 Mar 2021 14:53:19

US3012171

Folder: SAE USA-US006-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:42

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:45:28
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:04:08
User entered 'USA-US006-2021-MRNA-1273-P301000007'	System	16 Mar 2021 14:52:20

US3012171

Folder: SAE USA-US006-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:42

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:45:28
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 15:04:08
User entered 'Yes (Y)'	System	16 Mar 2021 14:52:20

US3012171

Folder: SAE USA-US006-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:42

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:45:28
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:04:08
User entered 'No (N)'	System	16 Mar 2021 14:52:20

US3012171

Folder: SAE USA-US006-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:42

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:45:28
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:04:08
User entered 'No (N)'	System	16 Mar 2021 14:52:20

US3012171

Folder: SAE USA-US006-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:42

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:45:28
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:04:08
User entered 'Yes (Y)'	System	16 Mar 2021 14:52:20

US3012171

Folder: SAE USA-US006-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:42

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:45:28
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:04:08
User entered 'No (N)'	System	16 Mar 2021 14:52:20

US3012171

Folder: SAE USA-US006-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:42

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:45:28
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:04:08
User entered 'No (N)'	System	16 Mar 2021 14:52:20

US3012171

Folder: SAE USA-US006-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:42

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:45:28
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:04:08
User entered 'No (N)'	System	16 Mar 2021 14:52:20

US3012171

Folder: SAE USA-US006-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:42

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:45:28
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:04:08
User entered 'Laurence'	System	16 Mar 2021 14:52:20

US3012171

Folder: SAE USA-US006-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:42

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:45:28
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:04:08
User entered 'Chu'	System	16 Mar 2021 14:52:20

US3012171

Folder: SAE USA-US006-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:42

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:45:28
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:04:08
User entered '3100 Red River Street'	System	16 Mar 2021 14:52:20

US3012171

Folder: SAE USA-US006-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:42

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:45:28
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 15:04:08
User entered 'Austin'	System	16 Mar 2021 14:52:20

US3012171

Folder: SAE USA-US006-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:42

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:45:28
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:04:08
User entered 'TX'	System	16 Mar 2021 14:52:20

US3012171

Folder: SAE USA-US006-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:42

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:45:28
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:04:08
User entered '78705'	System	16 Mar 2021 14:52:20

US3012171

Folder: SAE USA-US006-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:42

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:45:28
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:04:08
User entered 'US'	System	16 Mar 2021 14:53:19

US3012171

Folder: SAE USA-US006-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:42

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	14 Apr 2021 12:53:51
User entered '5'	System	13 Apr 2021 17:29:23
User entered '4'	System	09 Apr 2021 13:39:32
User entered '3'	System	29 Mar 2021 13:27:44
User entered '2'	System	25 Mar 2021 14:42:42
User entered '1'	System	16 Mar 2021 14:53:19

US3012171

Folder: SAE USA-US006-2021-MRNA-1273-P301000007

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 14:47:42

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:45:28
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered '16/Mar/2021 10:53'	(b) (4) System	16 Mar 2021 14:53:19

US3012171

Folder: SAE USA-US006-2021-MRNA-1273-P301000007

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 14:47:42

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 19:45:28
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 15:04:08
User entered 'I'	(b) (4), (b) (6)	16 Mar 2021 14:53:19

US3012171

Folder: SAE USA-US006-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:42

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:45:28
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:04:08
User entered 'USA-US006-2021-MRNA-1273-P301000007'	System	16 Mar 2021 14:52:20

US3012171

Folder: SAE USA-US006-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:42

[Serious](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:45:28
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:04:08
User entered 'Yes (Y)'	System	16 Mar 2021 14:52:20

US3012171

Folder: SAE USA-US006-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:42

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:45:28
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:04:08
User entered 'No (N)'	System	16 Mar 2021 14:52:20

US3012171

Folder: SAE USA-US006-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:42

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:45:28
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:04:08
User entered 'No (N)'	System	16 Mar 2021 14:52:20

US3012171

Folder: SAE USA-US006-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:42

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:45:28
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:04:08
User entered 'Yes (Y)'	System	16 Mar 2021 14:52:20

US3012171

Folder: SAE USA-US006-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:42

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:45:28
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:04:08
User entered 'No (N)'	System	16 Mar 2021 14:52:20

US3012171

Folder: SAE USA-US006-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:42

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:45:28
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:04:08
User entered 'No (N)'	System	16 Mar 2021 14:52:20

US3012171

Folder: SAE USA-US006-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:42

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:45:28
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:04:08
User entered 'No (N)'	System	16 Mar 2021 14:52:20

US3012171

Folder: SAE USA-US006-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:42

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:45:28
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:04:08
User entered 'Laurence'	System	16 Mar 2021 14:52:20

US3012171

Folder: SAE USA-US006-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:42

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:45:28
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:04:08
User entered 'Chu'	System	16 Mar 2021 14:52:20

US3012171

Folder: SAE USA-US006-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:42

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:45:28
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 15:04:08
User entered '3100 Red River Street'	System	16 Mar 2021 14:52:20

US3012171

Folder: SAE USA-US006-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:42

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:45:28
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:04:08
User entered 'Austin'	System	16 Mar 2021 14:52:20

US3012171

Folder: SAE USA-US006-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:42

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:45:28
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:04:08
User entered 'TX'	System	16 Mar 2021 14:52:20

US3012171

Folder: SAE USA-US006-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:42

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:45:28
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:04:08
User entered '78705'	System	16 Mar 2021 14:52:20

US3012171

Folder: SAE USA-US006-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:42

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:45:28
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:04:08
User entered 'US'	System	16 Mar 2021 14:53:19

US3012171

Folder: SAE USA-US006-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:42

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	14 Apr 2021 12:53:51
User entered '5'	System	13 Apr 2021 17:29:23
User entered '4'	System	09 Apr 2021 13:39:32
User entered '3'	System	29 Mar 2021 13:27:44
User entered '2'	System	25 Mar 2021 14:42:42
User entered '1'	System	16 Mar 2021 14:53:19

US3012171

Folder: SAE USA-US006-2021-MRNA-1273-P301000007

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 14:47:42

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:45:28
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered '25/Mar/2021 07:42'	(b) (4) System	25 Mar 2021 14:42:42

US3012171

Folder: SAE USA-US006-2021-MRNA-1273-P301000007

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 14:47:42

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 19:45:28
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 13:27:33
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
User entered 'I'	(b) (4), (b) (6)	25 Mar 2021 14:42:42

US3012171

Folder: SAE USA-US006-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:42

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:45:28
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:04:08
User entered 'USA-US006-2021-MRNA-1273-P301000007'	System	16 Mar 2021 14:52:20

US3012171

Folder: SAE USA-US006-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:42

[Serious](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:45:28
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:04:08
User entered 'Yes (Y)'	System	16 Mar 2021 14:52:20

US3012171

Folder: SAE USA-US006-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:42

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:45:28
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:04:08
User entered 'No (N)'	System	16 Mar 2021 14:52:20

US3012171

Folder: SAE USA-US006-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:42

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:45:28
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:04:08
User entered 'No (N)'	System	16 Mar 2021 14:52:20

US3012171

Folder: SAE USA-US006-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:42

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:45:28
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:04:08
User entered 'Yes (Y)'	System	16 Mar 2021 14:52:20

US3012171

Folder: SAE USA-US006-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:42

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:45:28
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:04:08
User entered 'No (N)'	System	16 Mar 2021 14:52:20

US3012171

Folder: SAE USA-US006-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:42

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:45:28
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:04:08
User entered 'No (N)'	System	16 Mar 2021 14:52:20

US3012171

Folder: SAE USA-US006-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:42

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:45:28
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:04:08
User entered 'No (N)'	System	16 Mar 2021 14:52:20

US3012171

Folder: SAE USA-US006-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:42

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:45:28
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:04:08
User entered 'Laurence'	System	16 Mar 2021 14:52:20

US3012171

Folder: SAE USA-US006-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:42

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:45:28
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:04:08
User entered 'Chu'	System	16 Mar 2021 14:52:20

US3012171

Folder: SAE USA-US006-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:42

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:45:28
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 15:04:08
User entered '3100 Red River Street'	System	16 Mar 2021 14:52:20

US3012171

Folder: SAE USA-US006-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:42

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:45:28
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 15:04:08
User entered 'Austin'	System	16 Mar 2021 14:52:20

US3012171

Folder: SAE USA-US006-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:42

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:45:28
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:04:08
User entered 'TX'	System	16 Mar 2021 14:52:20

US3012171

Folder: SAE USA-US006-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:42

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:45:28
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:04:08
User entered '78705'	System	16 Mar 2021 14:52:20

US3012171

Folder: SAE USA-US006-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:42

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:45:28
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:04:08
User entered 'US'	System	16 Mar 2021 14:53:19

US3012171

Folder: SAE USA-US006-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:42

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	14 Apr 2021 12:53:51
User entered '5'	System	13 Apr 2021 17:29:23
User entered '4'	System	09 Apr 2021 13:39:32
User entered '3'	System	29 Mar 2021 13:27:44
User entered '2'	System	25 Mar 2021 14:42:42
User entered '1'	System	16 Mar 2021 14:53:19

US3012171

Folder: SAE USA-US006-2021-MRNA-1273-P301000007

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 14:47:42

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:45:28
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 14:53:57
User entered '29/Mar/2021 08:27'	(b) (4) System	29 Mar 2021 13:27:44

US3012171

Folder: SAE USA-US006-2021-MRNA-1273-P301000007

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 14:47:42

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	14 Apr 2021 12:53:41
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:45:28
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 14:53:57
User entered 'I'	(b) (4), (b) (6)	29 Mar 2021 13:27:44

US3012171

Folder: SAE USA-US006-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:42

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:45:28
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:04:08
User entered 'USA-US006-2021-MRNA-1273-P301000007'	System	16 Mar 2021 14:52:20

US3012171

Folder: SAE USA-US006-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:42

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:45:28
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 15:04:08
User entered 'Yes (Y)'	System	16 Mar 2021 14:52:20

US3012171

Folder: SAE USA-US006-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:42

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:45:28
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:04:08
User entered 'No (N)'	System	16 Mar 2021 14:52:20

US3012171

Folder: SAE USA-US006-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:42

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:45:28
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:04:08
User entered 'No (N)'	System	16 Mar 2021 14:52:20

US3012171

Folder: SAE USA-US006-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:42

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:45:28
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:04:08
User entered 'Yes (Y)'	System	16 Mar 2021 14:52:20

US3012171

Folder: SAE USA-US006-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:42

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:45:28
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:04:08
User entered 'No (N)'	System	16 Mar 2021 14:52:20

US3012171

Folder: SAE USA-US006-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:42

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:45:28
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:04:08
User entered 'No (N)'	System	16 Mar 2021 14:52:20

US3012171

Folder: SAE USA-US006-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:42

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:45:28
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:04:08
User entered 'No (N)'	System	16 Mar 2021 14:52:20

US3012171

Folder: SAE USA-US006-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:42

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:45:28
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:04:08
User entered 'Laurence'	System	16 Mar 2021 14:52:20

US3012171

Folder: SAE USA-US006-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:42

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:45:28
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:04:08
User entered 'Chu'	System	16 Mar 2021 14:52:20

US3012171

Folder: SAE USA-US006-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:42

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:45:28
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:04:08
User entered '3100 Red River Street'	System	16 Mar 2021 14:52:20

US3012171

Folder: SAE USA-US006-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:42

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:45:28
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 15:04:08
User entered 'Austin'	System	16 Mar 2021 14:52:20

US3012171

Folder: SAE USA-US006-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:42

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:45:28
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:04:08
User entered 'TX'	System	16 Mar 2021 14:52:20

US3012171

Folder: SAE USA-US006-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:42

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:45:28
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:04:08
User entered '78705'	System	16 Mar 2021 14:52:20

US3012171

Folder: SAE USA-US006-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:42

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:45:28
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:04:08
User entered 'US'	System	16 Mar 2021 14:53:19

US3012171

Folder: SAE USA-US006-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:42

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	14 Apr 2021 12:53:51
User entered '5'	System	13 Apr 2021 17:29:23
User entered '4'	System	09 Apr 2021 13:39:32
User entered '3'	System	29 Mar 2021 13:27:44
User entered '2'	System	25 Mar 2021 14:42:42
User entered '1'	System	16 Mar 2021 14:53:19

US3012171

Folder: SAE USA-US006-2021-MRNA-1273-P301000007

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 14:47:42

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:45:28
User signature succeeded.	Laurence Chu (b) (4)	09 Apr 2021 20:42:01
User entered '09/Apr/2021 09:39'	(b) (4) System	09 Apr 2021 13:39:32

US3012171

Folder: SAE USA-US006-2021-MRNA-1273-P301000007

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 14:47:42

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	14 Apr 2021 12:53:41
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:45:28
User signature succeeded.	Laurence Chu (b) (4)	09 Apr 2021 20:42:01
User entered 'I'	(b) (4), (b) (6)	09 Apr 2021 13:39:32

US3012171

Folder: SAE USA-US006-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:42

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:45:28
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:04:08
User entered 'USA-US006-2021-MRNA-1273-P301000007'	System	16 Mar 2021 14:52:20

US3012171

Folder: SAE USA-US006-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:42

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:45:28
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:04:08
User entered 'Yes (Y)'	System	16 Mar 2021 14:52:20

US3012171

Folder: SAE USA-US006-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:42

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:45:28
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:04:08
User entered 'No (N)'	System	16 Mar 2021 14:52:20

US3012171

Folder: SAE USA-US006-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:42

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:45:28
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:04:08
User entered 'No (N)'	System	16 Mar 2021 14:52:20

US3012171

Folder: SAE USA-US006-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:42

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:45:28
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:04:08
User entered 'Yes (Y)'	System	16 Mar 2021 14:52:20

US3012171

Folder: SAE USA-US006-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:42

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:45:28
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:04:08
User entered 'No (N)'	System	16 Mar 2021 14:52:20

US3012171

Folder: SAE USA-US006-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:42

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:45:28
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:04:08
User entered 'No (N)'	System	16 Mar 2021 14:52:20

US3012171

Folder: SAE USA-US006-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:42

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:45:28
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:04:08
User entered 'No (N)'	System	16 Mar 2021 14:52:20

US3012171

Folder: SAE USA-US006-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:42

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:45:28
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:04:08
User entered 'Laurence'	System	16 Mar 2021 14:52:20

US3012171

Folder: SAE USA-US006-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:42

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:45:28
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:04:08
User entered 'Chu'	System	16 Mar 2021 14:52:20

US3012171

Folder: SAE USA-US006-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:42

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:45:28
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:04:08
User entered '3100 Red River Street'	System	16 Mar 2021 14:52:20

US3012171

Folder: SAE USA-US006-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:42

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:45:28
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:04:08
User entered 'Austin'	System	16 Mar 2021 14:52:20

US3012171

Folder: SAE USA-US006-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:42

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:45:28
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:04:08
User entered 'TX'	System	16 Mar 2021 14:52:20

US3012171

Folder: SAE USA-US006-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:42

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:45:28
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:04:08
User entered '78705'	System	16 Mar 2021 14:52:20

US3012171

Folder: SAE USA-US006-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:42

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:45:28
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:04:08
User entered 'US'	System	16 Mar 2021 14:53:19

US3012171

Folder: SAE USA-US006-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:42

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	14 Apr 2021 12:53:51
User entered '5'	System	13 Apr 2021 17:29:23
User entered '4'	System	09 Apr 2021 13:39:32
User entered '3'	System	29 Mar 2021 13:27:44
User entered '2'	System	25 Mar 2021 14:42:42
User entered '1'	System	16 Mar 2021 14:53:19

US3012171

Folder: SAE USA-US006-2021-MRNA-1273-P301000007

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 14:47:42

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	15 Apr 2021 16:35:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:45:28
User entered '13/Apr/2021 10:29'	System	13 Apr 2021 17:29:23

US3012171

Folder: SAE USA-US006-2021-MRNA-1273-P301000007

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 14:47:42

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	15 Apr 2021 16:35:55
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 12:53:41
DataPoint Verified.		13 Apr 2021 19:45:28
User entered '1' reason for change: Data Entry Error		13 Apr 2021 17:29:23
User entered '0'		13 Apr 2021 17:27:42

US3012171

Folder: SAE USA-US006-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:42

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:45:28
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:04:08
User entered 'USA-US006-2021-MRNA-1273-P301000007'	System	16 Mar 2021 14:52:20

US3012171

Folder: SAE USA-US006-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:42

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:45:28
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 15:04:08
User entered 'Yes (Y)'	System	16 Mar 2021 14:52:20

US3012171

Folder: SAE USA-US006-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:42

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:45:28
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:04:08
User entered 'No (N)'	System	16 Mar 2021 14:52:20

US3012171

Folder: SAE USA-US006-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:42

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:45:28
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:04:08
User entered 'No (N)'	System	16 Mar 2021 14:52:20

US3012171

Folder: SAE USA-US006-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:42

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:45:28
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:04:08
User entered 'Yes (Y)'	System	16 Mar 2021 14:52:20

US3012171

Folder: SAE USA-US006-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:42

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:45:28
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:04:08
User entered 'No (N)'	System	16 Mar 2021 14:52:20

US3012171

Folder: SAE USA-US006-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:42

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:45:28
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:04:08
User entered 'No (N)'	System	16 Mar 2021 14:52:20

US3012171

Folder: SAE USA-US006-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:42

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:45:28
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:04:08
User entered 'No (N)'	System	16 Mar 2021 14:52:20

US3012171

Folder: SAE USA-US006-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:42

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:45:28
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:04:08
User entered 'Laurence'	System	16 Mar 2021 14:52:20

US3012171

Folder: SAE USA-US006-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:42

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:45:28
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:04:08
User entered 'Chu'	System	16 Mar 2021 14:52:20

US3012171

Folder: SAE USA-US006-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:42

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:45:28
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:04:08
User entered '3100 Red River Street'	System	16 Mar 2021 14:52:20

US3012171

Folder: SAE USA-US006-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:42

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:45:28
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:04:08
User entered 'Austin'	System	16 Mar 2021 14:52:20

US3012171

Folder: SAE USA-US006-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:42

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:45:28
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:04:08
User entered 'TX'	System	16 Mar 2021 14:52:20

US3012171

Folder: SAE USA-US006-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:42

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:45:28
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:04:08
User entered '78705'	System	16 Mar 2021 14:52:20

US3012171

Folder: SAE USA-US006-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:42

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:45:28
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:56:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:04:08
User entered 'US'	System	16 Mar 2021 14:53:19

US3012171

Folder: SAE USA-US006-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:42

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	14 Apr 2021 12:53:51
User entered '5'	System	13 Apr 2021 17:29:23
User entered '4'	System	09 Apr 2021 13:39:32
User entered '3'	System	29 Mar 2021 13:27:44
User entered '2'	System	25 Mar 2021 14:42:42
User entered '1'	System	16 Mar 2021 14:53:19

US3012171

Folder: SAE USA-US006-2021-MRNA-1273-P301000007

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 14:47:42

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:07:58
User signature succeeded.	Laurence Chu (b) (4)	15 Apr 2021 16:35:55
User entered '14/Apr/2021 07:53'	(b) (4) System	14 Apr 2021 12:53:51

US3012171

Folder: SAE USA-US006-2021-MRNA-1273-P301000007

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 14:47:42

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)	15 Apr 2021 21:07:58
User signature succeeded.	Laurence Chu (b) (4)	15 Apr 2021 16:35:55
User entered 'I'	(b) (4), (b) (6)	14 Apr 2021 12:53:51