

US3322329 (Prod: DM Clinical Research - Texas Center For Drug Development - ERN - PPDS)

Generated By: KC Joubran

Generated On: 09 Jun 2021 17:04:12

All time stamps listed in this document are displayed in GMT

US3322329

Form: Participant Creation

Data signed: (b) (4) 26 Feb 2021 03:58:31

Generated On: 09 Jun 2021 17:04:12

Participant ID

US3322329

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

US3322329

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 26 Feb 2021 03:58:32

Generated On: 09 Jun 2021 17:04:12

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	12 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 26 Feb 2021 03:58:32

Generated On: 09 Jun 2021 17:04:12

Date of Birth (MMM yyyy)	(b) (6) 1968
Age	51
Age Units	YEARS
Age (Derived)	51
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 26 Feb 2021 03:58:32

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Date of Informed Consent (<i>dd MMM yyyy</i>)	12 SEP 2020
Month and Year of Informed Consent (derived)	SEP 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/>
	Amendment 2 <input type="radio"/>
	Amendment 3 <input checked="" type="radio"/>
	Amendment 4 <input type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 26 Feb 2021 03:58:32

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 26 Feb 2021 03:58:32

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 26 Feb 2021 03:58:32

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Condition	HYSTERECTOMY
Start date (dd MMM yyyy)	UN UNK 2007
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2007
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2007
Start Year (derived)	2007
Stop Month and Year (derived)	JAN 2007
Stop Year (derived)	2007

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 26 Feb 2021 03:58:32

Generated On: 09 Jun 2021 17:04:12

Condition	FOOT SURGERY
Start date (dd MMM yyyy)	UN UNK 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 UNK 2018
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	JAN 2018
Stop Year (derived)	2018

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 26 Feb 2021 03:58:32

Generated On: 09 Jun 2021 17:04:12

Condition	CERVICAL DYSPLASIA
Start date (dd MMM yyyy)	UN UNK 2007
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2007
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2007
Start Year (derived)	2007
Stop Month and Year (derived)	JAN 2007
Stop Year (derived)	2007

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 26 Feb 2021 03:58:32

Generated On: 09 Jun 2021 17:04:12

Condition	TENNIS INJURY-LEFT FOOT
Start date (dd MMM yyyy)	UN UNK 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 UNK 2018
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	JAN 2018
Stop Year (derived)	2018

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 26 Feb 2021 03:58:32

Generated On: 09 Jun 2021 17:04:12

Condition	POST MENOPAUSAL
Start date (dd MMM yyyy)	UN UNK 2014
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 2014
Start Year (derived)	2014
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 26 Feb 2021 03:58:32

Generated On: 09 Jun 2021 17:04:12

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	12 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	10:15 (24 HR)
Vital Signs Date and Time (derived)	12 SEP 2020 10:15
Height (<i>xxx.x</i>)	73 in
Weight (<i>xxx.x</i>)	215.8 lb
BMI (<i>xxx.x</i>)	28.53091 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	ND - Not Done
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 26 Feb 2021 03:58:32

Generated On: 09 Jun 2021 17:04:12

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

12 SEP 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 26 Feb 2021 03:58:32

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Date of assessment (dd MMM yyyy) 12 SEP 2020

Is the participant of childbearing potential? Yes ☐
No ☒

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

If Partner medically sterile or Other, specify _____

If Surgically sterile, date of surgery (dd MMM yyyy) UN UNK 2007

Date of surgery unknown False

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

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 26 Feb 2021 03:58:32

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Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

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) 26 Feb 2021 03:58:32

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 26 Feb 2021 03:58:32

Generated On: 09 Jun 2021 17:04:12

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	12 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 26 Feb 2021 03:58:32

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What was the date of randomization? (dd MMM yyyy) 12 SEP 2020

What was the participant's randomization number? 113720

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) 26 Feb 2021 03:58:32

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Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 26 Feb 2021 03:58:32

Generated On: 09 Jun 2021 17:04:12

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)	12 SEP 2020
Time of assessment (00:00-23:59)	10:30 (24 HR)
Vital Signs Date and Time (derived)	12 SEP 2020 10:30
Temperature (xxx.x)	98.4 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	62 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	121 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 26 Feb 2021 03:58:32

Generated On: 09 Jun 2021 17:04:12

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)	12 SEP 2020
Time of assessment (00:00-23:59)	12:37 (24 HR)
Vital Signs Date and Time (derived)	12 SEP 2020 12:37
Temperature (xxx.x)	94.8 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	60 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)	85 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 26 Feb 2021 03:58:32

Generated On: 09 Jun 2021 17:04:12

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) 26 Feb 2021 03:58:32

Generated On: 09 Jun 2021 17:04:12

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

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

What was the treatment time? (00:00-23:59) 12:07 (24 HR)

Treatment Date and Time (derived) 12 SEP 2020 12:07

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) 26 Feb 2021 03:58:32

Generated On: 09 Jun 2021 17:04:12

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	12 SEP 2020
Collection time (00:00-23:59)	11:40 (24 HR)
Collection date and time (derived)	12 SEP 2020 11:40

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 26 Feb 2021 03:58:32

Generated On: 09 Jun 2021 17:04:12

Collection date (dd MMM yyyy)			12 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:35	12 SEP 2020 11:35
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 03:58:32

Generated On: 09 Jun 2021 17:04:12

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:04:12

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

94.8 °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

12 SEP 2020 12:48

PC Open Date & Time

12 SEP 2020 12:27

PC Close Date & Time

12 SEP 2020 14:57

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.0 °F

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

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

PC Time Stamp	12 SEP 2020 17:31
PC Open Date & Time	12 SEP 2020 15:52
PC Close Date & Time	13 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °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

13 SEP 2020 16:52

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 SEP 2020 14:57

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3322329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 SEP 2020 15:24

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was TEMPERATURE taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.0 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

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

PC Time Stamp	16 SEP 2020 21:18
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

US3322329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:04:12

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

97.3 °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 SEP 2020 09:44

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3322329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:04:12

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

19 SEP 2020 07:28

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3322329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:04:12

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

12 SEP 2020 12:50

PC Open Date & Time

12 SEP 2020 12:27

PC Close Date & Time

12 SEP 2020 14:57

US3322329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

12 SEP 2020 17:32

PC Open Date & Time

12 SEP 2020 15:52

PC Close Date & Time

13 SEP 2020 11:59

US3322329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:04:12

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

20

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

13 SEP 2020 16:57

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3322329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☒

No ☐

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

25

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

14 SEP 2020 14:57

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3322329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

DAY 4

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

15 SEP 2020 15:40

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3322329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

16 SEP 2020 21:18

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3322329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

18 SEP 2020 09:44

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3322329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

19 SEP 2020 07:28

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:04:12

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 ☐

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:04:12

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

No ☒

Yes ☐

PC Time stamp	12 SEP 2020 12:50
PC Open Date & Time	12 SEP 2020 12:27
PC Close Date & Time	12 SEP 2020 14:57

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Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:04:12

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 ☐

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:04:12

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

No ☒

Yes ☐

PC Time stamp	12 SEP 2020 17:33
PC Open Date & Time	12 SEP 2020 15:52
PC Close Date & Time	13 SEP 2020 11:59

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:04:12

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

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

DAY 3

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:04:12

Yes <input type="checkbox"/>	
PC Time stamp	14 SEP 2020 14:58
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:04:12

Yes <input type="checkbox"/>	
PC Time stamp	15 SEP 2020 15:40
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

53 of 2938

EAB) (1725)

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:04:12

Yes <input type="checkbox"/>	
PC Time stamp	16 SEP 2020 21:26
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:04:12

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 ☒

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:04:12

Yes <input type="checkbox"/>	
PC Time stamp	18 SEP 2020 09:45
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:04:12

Yes <input type="checkbox"/>	
PC Time stamp	19 SEP 2020 07:29
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

US3322329

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your **MUSCLE**

ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 19 SEP 2020 12:35

PC Open Date & Time 19 SEP 2020 12:00

PC Close Date & Time 20 SEP 2020 11:59

US3322329

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your **MUSCLE**

None ☒

ACHES ALL OVER BODY

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 20 SEP 2020 12:30

PC Open Date & Time 20 SEP 2020 12:00

PC Close Date & Time 21 SEP 2020 11:59

US3322329

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	19 SEP 2020 12:35
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

US3322329

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT	DAY 9
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	20 SEP 2020 12:30
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

US3322329

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 26 Feb 2021 03:58:32

Generated On: 09 Jun 2021 17:04:12

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3322329

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 03:58:32

Generated On: 09 Jun 2021 17:04:12

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3322329

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 26 Feb 2021 03:58:32

Generated On: 09 Jun 2021 17:04:12

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3322329

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 03:58:32

Generated On: 09 Jun 2021 17:04:12

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3322329

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 26 Feb 2021 03:58:32

Generated On: 09 Jun 2021 17:04:12

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

US3322329

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 03:58:32

Generated On: 09 Jun 2021 17:04:12

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3322329

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 26 Feb 2021 03:58:33

Generated On: 09 Jun 2021 17:04:12

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

US3322329

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 26 Feb 2021 03:58:33

Generated On: 09 Jun 2021 17:04:12

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 OCT 2020
Time of assessment (00:00-23:59)	08:50 (24 HR)
Vital Signs Date and Time (derived)	15 OCT 2020 08:50
Temperature (xxx.x)	96.8 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	60 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	13 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	83 mmHg
Diastolic Blood Pressure units	MMHG

US3322329

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 26 Feb 2021 03:58:33

Generated On: 09 Jun 2021 17:04:12

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	15 OCT 2020
Time of assessment (00:00-23:59)	10:26 (24 HR)
Vital Signs Date and Time (derived)	15 OCT 2020 10:26
Temperature (xxx.x)	97.0 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	69 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	135 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	85 mmHg
Diastolic Blood Pressure units	MMHG

US3322329

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Feb 2021 03:58:33

Generated On: 09 Jun 2021 17:04:12

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

15 OCT 2020

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

US3322329

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 26 Feb 2021 03:58:33

Generated On: 09 Jun 2021 17:04:12

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 OCT 2020

What was the treatment time? (00:00-23:59) 09:56 (24 HR)

Treatment Date and Time (derived) 15 OCT 2020 09:56

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

US3322329

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Feb 2021 03:58:33

Generated On: 09 Jun 2021 17:04:12

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

15 OCT 2020

Collection time (00:00-23:59)

09:25 (24 HR)

Collection date and time (derived)

15 OCT 2020 09:25

US3322329

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 26 Feb 2021 03:58:32

Generated On: 09 Jun 2021 17:04:12

Collection date (dd MMM yyyy)			15 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:20	15 OCT 2020 09:20
Nasopharyngeal Swab 2	No		

US3322329

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 03:58:32

Generated On: 09 Jun 2021 17:04:12

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3322329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒
No ☐

Please record your **TEMPERATURE** in °F

97.0 °F

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

Yes ☐
No ☒

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

PC Time Stamp 15 OCT 2020 10:25

PC Open Date & Time 15 OCT 2020 10:16

PC Close Date & Time 15 OCT 2020 12:46

US3322329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.9 °F

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

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

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

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

PC Time Stamp 16 OCT 2020 02:01

PC Open Date & Time 15 OCT 2020 13:41

PC Close Date & Time 16 OCT 2020 11:59

US3322329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:04:12

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

98.2 °F

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

Yes ☒

No ☐

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

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

16 OCT 2020 13:28

PC Open Date & Time

16 OCT 2020 12:00

PC Close Date & Time

17 OCT 2020 11:59

US3322329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:04:12

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.3 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

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

PC Time Stamp	17 OCT 2020 12:03
PC Open Date & Time	17 OCT 2020 12:00
PC Close Date & Time	18 OCT 2020 11:59

US3322329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:04:12

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

96.8 °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 OCT 2020 16:19

PC Open Date & Time

18 OCT 2020 12:00

PC Close Date & Time

19 OCT 2020 11:59

US3322329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:04:12

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

97.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 OCT 2020 22:52

PC Open Date & Time

19 OCT 2020 12:00

PC Close Date & Time

20 OCT 2020 11:59

US3322329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:04:12

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

20 OCT 2020 23:32

PC Open Date & Time

20 OCT 2020 12:00

PC Close Date & Time

21 OCT 2020 11:59

US3322329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:04:12

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

97.8 °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 OCT 2020 22:20

PC Open Date & Time

21 OCT 2020 12:00

PC Close Date & Time

22 OCT 2020 11:59

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:04:12

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

15 OCT 2020 10:26

PC Open Date & Time

15 OCT 2020 10:16

PC Close Date & Time

15 OCT 2020 12:46

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:04:12

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

20

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

16 OCT 2020 02:02

PC Open Date & Time

15 OCT 2020 13:41

PC Close Date & Time

16 OCT 2020 11:59

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:04:12

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

76

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

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

16 OCT 2020 13:22

PC Open Date & Time

16 OCT 2020 12:00

PC Close Date & Time

17 OCT 2020 11:59

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☒

No ☐

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

100

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

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

Yes ☒

No ☐

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

125

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

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

17 OCT 2020 12:01

PC Open Date & Time

17 OCT 2020 12:00

PC Close Date & Time

18 OCT 2020 11:59

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

DAY 4

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☒

No ☐

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

64

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

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

Yes ☒

No ☐

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

55

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

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

18 OCT 2020 16:20

PC Open Date & Time

18 OCT 2020 12:00

PC Close Date & Time

19 OCT 2020 11:59

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

DAY 5

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☒

No ☐

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

50

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

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

Yes ☒

No ☐

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

50

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

19 OCT 2020 22:54

PC Open Date & Time

19 OCT 2020 12:00

PC Close Date & Time

20 OCT 2020 11:59

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

DAY 6

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☒

No ☐

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

40

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

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

Yes ☒

No ☐

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

25

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

20 OCT 2020 23:33

PC Open Date & Time

20 OCT 2020 12:00

PC Close Date & Time

21 OCT 2020 11:59

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☒

No ☐

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

35

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

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

Yes ☒

No ☐

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

20

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

21 OCT 2020 22:21

PC Open Date & Time

21 OCT 2020 12:00

PC Close Date & Time

22 OCT 2020 11:59

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:04:12

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 ☐

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:04:12

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

No ☒

Yes ☐

PC Time stamp	15 OCT 2020 10:26
PC Open Date & Time	15 OCT 2020 10:16
PC Close Date & Time	15 OCT 2020 12:46

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:04:12

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 ☐

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:04:12

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

No ☒

Yes ☐

PC Time stamp	16 OCT 2020 02:03
PC Open Date & Time	15 OCT 2020 13:41
PC Close Date & Time	16 OCT 2020 11:59

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:04:12

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 ☒

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:04:12

Yes <input type="checkbox"/>	
PC Time stamp	16 OCT 2020 13:23
PC Open Date & Time	16 OCT 2020 12:00
PC Close Date & Time	17 OCT 2020 11:59

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

DAY 3

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☐

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:04:12

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

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:04:12

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 ☒

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:04:12

Yes <input type="checkbox"/>	
PC Time stamp	18 OCT 2020 16:21
PC Open Date & Time	18 OCT 2020 12:00
PC Close Date & Time	19 OCT 2020 11:59

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:04:12

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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Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:04:12

Yes <input type="checkbox"/>	
PC Time stamp	19 OCT 2020 22:55
PC Open Date & Time	19 OCT 2020 12:00
PC Close Date & Time	20 OCT 2020 11:59

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:04:12

Yes <input type="checkbox"/>	
PC Time stamp	20 OCT 2020 23:45
PC Open Date & Time	20 OCT 2020 12:00
PC Close Date & Time	21 OCT 2020 11:59

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:04:12

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

US3322329

Folder: Diary Dose 2 (1)

Form: Redness_Day(8)

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT	DAY 8
Is there any REDNESS AT INJECTION SITE?	Yes <input type="checkbox"/>
	No <input checked="" type="checkbox"/>
PC Time Stamp	22 OCT 2020 13:21
PC Open Date & Time	22 OCT 2020 12:00
PC Close Date & Time	23 OCT 2020 11:59

US3322329

Folder: Diary Dose 2 (1)

Form: Swelling_Day(8)

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

DAY 8

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

Yes ☒

No ☐

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

25

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

PC Time stamp 22 OCT 2020 13:22

PC Open Date & Time 22 OCT 2020 12:00

PC Close Date & Time 23 OCT 2020 11:59

US3322329

Folder: Diary Dose 2 (1)

Form: Swelling_Day(9)

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT	DAY 9
Is there any SWELLING/HARDNESS AT INJECTION SITE?	Yes <input type="checkbox"/>
	No <input checked="" type="checkbox"/>
PC Time stamp	23 OCT 2020 14:21
PC Open Date & Time	23 OCT 2020 12:00
PC Close Date & Time	24 OCT 2020 11:59

US3322329

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	22 OCT 2020 13:22
PC Open Date & Time	22 OCT 2020 12:00
PC Close Date & Time	23 OCT 2020 11:59

US3322329

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT	DAY 9
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	23 OCT 2020 14:21
PC Open Date & Time	23 OCT 2020 12:00
PC Close Date & Time	24 OCT 2020 11:59

US3322329

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 26 Feb 2021 03:58:32

Generated On: 09 Jun 2021 17:04:12

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3322329

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 03:58:32

Generated On: 09 Jun 2021 17:04:12

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3322329

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 26 Feb 2021 03:58:32

Generated On: 09 Jun 2021 17:04:12

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3322329

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 03:58:32

Generated On: 09 Jun 2021 17:04:12

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3322329

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 26 Feb 2021 03:58:32

Generated On: 09 Jun 2021 17:04:12

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

5 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3322329

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 03:58:32

Generated On: 09 Jun 2021 17:04:12

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3322329

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 26 Feb 2021 03:58:33

Generated On: 09 Jun 2021 17:04:12

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	17 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3322329

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 26 Feb 2021 03:58:33

Generated On: 09 Jun 2021 17:04:12

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	17 NOV 2020
Time of assessment (00:00-23:59)	09:30 (24 HR)
Vital Signs Date and Time (derived)	17 NOV 2020 09:30
Temperature (xxx.x)	96.6 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	63 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	90 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3322329

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Feb 2021 03:58:33

Generated On: 09 Jun 2021 17:04:12

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

17 NOV 2020

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

US3322329

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Feb 2021 03:58:33

Generated On: 09 Jun 2021 17:04:12

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	17 NOV 2020
Collection time (00:00-23:59)	10:24 (24 HR)
Collection date and time (derived)	17 NOV 2020 10:24

US3322329

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 03:58:33

Generated On: 09 Jun 2021 17:04:12

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3322329

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

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

12 NOV 2020 09:07:27

Patient Cloud Open Date & Time

12 NOV 2020 00:01

Patient Cloud Close Date & Time

16 NOV 2020 23:59

US3322329

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

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

19 NOV 2020 14:42:48

Patient Cloud Open Date & Time

19 NOV 2020 00:01

Patient Cloud Close Date & Time

23 NOV 2020 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT	DAY 75
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	23 NOV 2020 06:45:49
Patient Cloud Open Date & Time	23 NOV 2020 00:01
Patient Cloud Close Date & Time	27 NOV 2020 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	03 DEC 2020 07:41:13
Patient Cloud Open Date & Time	30 NOV 2020 00:01
Patient Cloud Close Date & Time	04 DEC 2020 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	10 DEC 2020 08:56:56
Patient Cloud Open Date & Time	07 DEC 2020 00:01
Patient Cloud Close Date & Time	11 DEC 2020 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	16 DEC 2020 14:33:00
Patient Cloud Open Date & Time	14 DEC 2020 00:01
Patient Cloud Close Date & Time	18 DEC 2020 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

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

21 DEC 2020 08:34:40

Patient Cloud Open Date & Time

21 DEC 2020 00:01

Patient Cloud Close Date & Time

25 DEC 2020 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	31 DEC 2020 09:06:37
Patient Cloud Open Date & Time	28 DEC 2020 00:01
Patient Cloud Close Date & Time	01 JAN 2021 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

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

05 JAN 2021 10:29:04

Patient Cloud Open Date & Time

04 JAN 2021 00:01

Patient Cloud Close Date & Time

08 JAN 2021 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	11 JAN 2021 08:50:17
Patient Cloud Open Date & Time	11 JAN 2021 00:01
Patient Cloud Close Date & Time	15 JAN 2021 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

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 checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	19 JAN 2021 15:26:26
Patient Cloud Open Date & Time	18 JAN 2021 00:01
Patient Cloud Close Date & Time	22 JAN 2021 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

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

25 JAN 2021 00:01:51

Patient Cloud Open Date & Time

25 JAN 2021 00:01

Patient Cloud Close Date & Time

29 JAN 2021 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 FEB 2021 12:00:53

Patient Cloud Open Date & Time

01 FEB 2021 00:01

Patient Cloud Close Date & Time

05 FEB 2021 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 FEB 2021 00:01:58

Patient Cloud Open Date & Time

08 FEB 2021 00:01

Patient Cloud Close Date & Time

12 FEB 2021 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

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

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

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

[Patient Cloud Close Date & Time](#)

19 FEB 2021 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	22 FEB 2021 16:00:32
Patient Cloud Open Date & Time	22 FEB 2021 00:01
Patient Cloud Close Date & Time	26 FEB 2021 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

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

02 MAR 2021 17:18:35

Patient Cloud Open Date & Time

01 MAR 2021 00:01

Patient Cloud Close Date & Time

05 MAR 2021 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 MAR 2021 18:26:36

Patient Cloud Open Date & Time

08 MAR 2021 00:01

Patient Cloud Close Date & Time

12 MAR 2021 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	16 MAR 2021 17:51:55
Patient Cloud Open Date & Time	15 MAR 2021 00:01
Patient Cloud Close Date & Time	19 MAR 2021 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

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

22 MAR 2021 05:02:38

Patient Cloud Open Date & Time

22 MAR 2021 00:01

Patient Cloud Close Date & Time

26 MAR 2021 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

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

29 MAR 2021 15:40:44

Patient Cloud Open Date & Time

29 MAR 2021 00:01

Patient Cloud Close Date & Time

02 APR 2021 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

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 type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	True
Chills	True
Cough	False
Shortness of breath	False
Difficulty breathing	False
Fatigue	True
Muscle aches	False
Body aches	False
Headache	False
New loss of taste	False
New loss of smell	False
Sore throat	False
Congestion	False
Runny nose	False
Nausea	True
Vomiting	False
Diarrhea	False
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	05 APR 2021 13:52:47
Patient Cloud Open Date & Time	05 APR 2021 00:01
PRODUCTION RELEASE (v12.003 EAB) (1725)	
147 of 2938	

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Close Date & Time](#)

09 APR 2021 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

12 APR 2021 11:51:37

Patient Cloud Open Date & Time

12 APR 2021 00:01

Patient Cloud Close Date & Time

16 APR 2021 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

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

19 APR 2021 00:03:57

Patient Cloud Open Date & Time

19 APR 2021 00:01

Patient Cloud Close Date & Time

23 APR 2021 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 APR 2021 13:40:44

Patient Cloud Open Date & Time

26 APR 2021 00:01

Patient Cloud Close Date & Time

30 APR 2021 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

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

03 MAY 2021 06:47:02

Patient Cloud Open Date & Time

03 MAY 2021 00:01

Patient Cloud Close Date & Time

07 MAY 2021 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

DAY 243

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

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

[Patient Cloud Close Date & Time](#)

14 MAY 2021 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

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

[Patient Cloud Close Date & Time](#)

21 MAY 2021 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

DAY 257

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

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

[Patient Cloud Close Date & Time](#)

28 MAY 2021 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

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

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

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

[Patient Cloud Open Date & Time](#)

31 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

04 JUN 2021 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

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

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

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

[Patient Cloud Close Date & Time](#)

11 JUN 2021 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

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 <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"/>

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

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

[Patient Cloud Close Date & Time](#)

18 JUN 2021 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

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 ☐

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

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

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

DAY 292

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

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

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

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

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

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

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

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

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

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

[Patient Cloud Open Date & Time](#)

28 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

02 JUL 2021 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

DAY 299

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	05 JUL 2021 00:01
Patient Cloud Close Date & Time	09 JUL 2021 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

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 <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"/>

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

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

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

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 ☐

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

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

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

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"/>

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

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

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

DAY 327

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

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

[Patient Cloud Close Date & Time](#)

06 AUG 2021 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

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

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

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

[Patient Cloud Close Date & Time](#)

13 AUG 2021 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

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°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"/>

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 AUG 2021 00:01
Patient Cloud Close Date & Time	20 AUG 2021 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

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

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

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

Patient Cloud Open Date & Time	23 AUG 2021 00:01
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Patient Cloud Close Date & Time	27 AUG 2021 23:59
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US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

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 ☐

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

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

[Patient Cloud Open Date & Time](#)

30 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

03 SEP 2021 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

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 ☐

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

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

[Patient Cloud Open Date & Time](#)

06 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

10 SEP 2021 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

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 ☐

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

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

[Patient Cloud Open Date & Time](#)

13 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

17 SEP 2021 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

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 ☐

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

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

[Patient Cloud Open Date & Time](#)

20 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

24 SEP 2021 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

DAY 383

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

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

[Patient Cloud Open Date & Time](#)

27 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

01 OCT 2021 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

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

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

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

[Patient Cloud Close Date & Time](#)

08 OCT 2021 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

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 ☐

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 OCT 2021 00:01
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Patient Cloud Close Date & Time	15 OCT 2021 23:59
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US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

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 ☐
Yes ☐

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

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	18 OCT 2021 00:01
Patient Cloud Close Date & Time	22 OCT 2021 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

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"/>

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

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

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

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"/>

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

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

[Patient Cloud Open Date & Time](#)

01 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

05 NOV 2021 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

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

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

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

[Patient Cloud Open Date & Time](#)

08 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

12 NOV 2021 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

DAY 432

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

No ☐
Yes ☐

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

No ☐
Yes ☐

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

No ☐
Yes ☐

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

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

Chills

Cough

Shortness of breath

Difficulty breathing

Fatigue

Muscle aches

Body aches

Headache

New loss of taste

New loss of smell

Sore throat

Congestion

Runny nose

Nausea

Vomiting

Diarrhea

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

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

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

No ☐
Yes ☐

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 NOV 2021 00:01
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Patient Cloud Close Date & Time	19 NOV 2021 23:59
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US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

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

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

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

[Patient Cloud Close Date & Time](#)

26 NOV 2021 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

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"/>

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

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

[Patient Cloud Open Date & Time](#)

29 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

03 DEC 2021 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

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 ☐

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

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

[Patient Cloud Open Date & Time](#)

06 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

10 DEC 2021 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

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"/>

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	13 DEC 2021 00:01
Patient Cloud Close Date & Time	17 DEC 2021 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

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"/>

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	20 DEC 2021 00:01
Patient Cloud Close Date & Time	24 DEC 2021 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

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

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	27 DEC 2021 00:01
Patient Cloud Close Date & Time	31 DEC 2021 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

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"/>

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

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

03 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

07 JAN 2022 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

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"/>

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

14 JAN 2022 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

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="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"/>

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

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

[Patient Cloud Close Date & Time](#)

21 JAN 2022 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

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 ☐

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

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

[Patient Cloud Close Date & Time](#)

28 JAN 2022 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

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 ☐

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

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

[Patient Cloud Open Date & Time](#)

31 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

04 FEB 2022 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

DAY 516

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

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

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

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

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

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

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

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

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 FEB 2022 00:01
Patient Cloud Close Date & Time	11 FEB 2022 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

DAY 523

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

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

[Patient Cloud Close Date & Time](#)

18 FEB 2022 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

DAY 530

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

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

[Patient Cloud Close Date & Time](#)

25 FEB 2022 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

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 ☐

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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Date and time of submission

[Patient Cloud Open Date & Time](#)

28 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

04 MAR 2022 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

DAY 544

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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Date and time of submission

[Patient Cloud Open Date & Time](#)

07 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

11 MAR 2022 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

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 ☐

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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Date and time of submission

[Patient Cloud Open Date & Time](#)

14 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

18 MAR 2022 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

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 ☐

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

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

[Patient Cloud Close Date & Time](#)

25 MAR 2022 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

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 ☐

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

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

[Patient Cloud Open Date & Time](#)

28 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

01 APR 2022 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

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 ☐

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

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

[Patient Cloud Close Date & Time](#)

08 APR 2022 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

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 ☐

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 APR 2022 00:01
Patient Cloud Close Date & Time	15 APR 2022 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

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 ☐

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	18 APR 2022 00:01
Patient Cloud Close Date & Time	22 APR 2022 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

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 ☐

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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Date and time of submission

[Patient Cloud Open Date & Time](#)

25 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

29 APR 2022 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

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"/>

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

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

[Patient Cloud Close Date & Time](#)

06 MAY 2022 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT	DAY 607
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

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

[Patient Cloud Open Date & Time](#)

09 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

13 MAY 2022 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

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"/>

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

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

[Patient Cloud Open Date & Time](#)

16 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

20 MAY 2022 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

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"/>

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

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

[Patient Cloud Open Date & Time](#)

23 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

27 MAY 2022 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

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

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

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

[Patient Cloud Open Date & Time](#)

30 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

03 JUN 2022 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

DAY 635

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

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

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

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

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

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

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

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

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

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

[Patient Cloud Open Date & Time](#)

06 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

10 JUN 2022 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

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"/>

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

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

[Patient Cloud Open Date & Time](#)

13 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

17 JUN 2022 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

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"/>

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

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

[Patient Cloud Open Date & Time](#)

20 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

24 JUN 2022 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT	DAY 656
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

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

[Patient Cloud Open Date & Time](#)

27 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

01 JUL 2022 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

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 ☐

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

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

[Patient Cloud Open Date & Time](#)

04 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

08 JUL 2022 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

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

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JUL 2022 00:01
Patient Cloud Close Date & Time	15 JUL 2022 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

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 ☐

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	18 JUL 2022 00:01
Patient Cloud Close Date & Time	22 JUL 2022 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

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="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"/>

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

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

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

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"/>

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

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

[Patient Cloud Open Date & Time](#)

01 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

05 AUG 2022 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

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

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

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

[Patient Cloud Open Date & Time](#)

08 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

12 AUG 2022 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

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 ☐

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

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

Patient Cloud Open Date & Time	15 AUG 2022 00:01
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Patient Cloud Close Date & Time	19 AUG 2022 23:59
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US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

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 ☐

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

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

[Patient Cloud Open Date & Time](#)

22 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

26 AUG 2022 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

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

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

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

[Patient Cloud Open Date & Time](#)

29 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

02 SEP 2022 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT	DAY 726
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

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

[Patient Cloud Open Date & Time](#)

05 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

09 SEP 2022 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

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"/>

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

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

[Patient Cloud Open Date & Time](#)

12 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

16 SEP 2022 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

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"/>

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

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

[Patient Cloud Open Date & Time](#)

19 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

23 SEP 2022 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

DAY 747

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

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

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

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

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

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

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

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

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

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

[Patient Cloud Open Date & Time](#)

26 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

30 SEP 2022 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

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 ☐

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

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

[Patient Cloud Open Date & Time](#)

03 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

07 OCT 2022 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

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

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 OCT 2022 00:01
Patient Cloud Close Date & Time	14 OCT 2022 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

DAY 768

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

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

[Patient Cloud Open Date & Time](#)

17 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

21 OCT 2022 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

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 ☐

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	24 OCT 2022 00:01
Patient Cloud Close Date & Time	28 OCT 2022 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

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 ☐

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

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

[Patient Cloud Open Date & Time](#)

31 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

04 NOV 2022 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT	DAY 789
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

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

07 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

11 NOV 2022 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

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"/>

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

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

Patient Cloud Open Date & Time	14 NOV 2022 00:01
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Patient Cloud Close Date & Time	18 NOV 2022 23:59
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US3322329

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 17:04:12

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
Yes	No	02 MAR 2021 17:19:04

US3322329

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 26 Feb 2021 03:58:32

Generated On: 09 Jun 2021 17:04:12

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

07 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3322329

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 03:58:32

Generated On: 09 Jun 2021 17:04:12

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3322329

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 24 Mar 2021 22:08:27

Generated On: 09 Jun 2021 17:04:12

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3322329

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 03:58:32

Generated On: 09 Jun 2021 17:04:12

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3322329

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 26 Feb 2021 03:58:32

Generated On: 09 Jun 2021 17:04:12

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 09 FEB 2021

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

Comments

If Contact Not Made, please provide Comments

US3322329

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 03:58:32

Generated On: 09 Jun 2021 17:04:12

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3322329

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 23 Apr 2021 16:34:02

Generated On: 09 Jun 2021 17:04:12

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3322329

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 24 Mar 2021 22:08:27

Generated On: 09 Jun 2021 17:04:12

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3322329

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:04:12

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

Visit date (dd MMM yyyy)	_____
--------------------------	-------

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

Folder OID	_____
------------	-------

US3322329

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:04:12

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

US3322329

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:04:12

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.

US3322329

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:04:12

Was the sample collected?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Collection date (<i>dd MMM yyyy</i>)	<input type="text"/>
Collection time (<i>00:00-23:59</i>)	<input type="text"/>
Collection date and time (derived)	<input type="text"/>

US3322329

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:04:12

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: COVID-19 Contact

Data signed: (b) (4) 23 Apr 2021 16:34:01

Generated On: 09 Jun 2021 17:04:12

Date of Contact	05 APR 2021
Time of Contact	11:43
Date and Time of Contact (derived)	05 APR 2021 11:43
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>

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (1)

Data signed: (b) (4) 23 Apr 2021 16:34:02

Generated On: 09 Jun 2021 17:04:12

Symptom Day

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

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (1)

Data signed: (b) (4) 23 Apr 2021 16:34:02

Generated On: 09 Jun 2021 17:04:12

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

Date	29 MAR 2021
------	-------------

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

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

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

Temperature	100.4 F
-------------	---------

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

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

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

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EAB) (1725)

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Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (1)

Data signed: (b) (4) 23 Apr 2021 16:34:02

Generated On: 09 Jun 2021 17:04:12

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

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (1)

Data signed: (b) (4) 23 Apr 2021 16:34:02

Generated On: 09 Jun 2021 17:04:12

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

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (2)

Data signed: (b) (4) 23 Apr 2021 16:34:02

Generated On: 09 Jun 2021 17:04:12

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"/>

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (2)

Data signed: (b) (4) 23 Apr 2021 16:34:02

Generated On: 09 Jun 2021 17:04:12

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	30 MAR 2021	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
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 checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (2)

Data signed: (b) (4) 23 Apr 2021 16:34:02

Generated On: 09 Jun 2021 17:04:12

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

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (2)

Data signed: (b) (4) 23 Apr 2021 16:34:02

Generated On: 09 Jun 2021 17:04:12

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 ☐

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (3)

Data signed: (b) (4) 23 Apr 2021 16:34:02

Generated On: 09 Jun 2021 17:04:12

Symptom Day

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

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Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (3)

Data signed: (b) (4) 23 Apr 2021 16:34:02

Generated On: 09 Jun 2021 17:04:12

	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 MAR 2021
------	-------------

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

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

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

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

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

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

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

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (3)

Data signed: (b) (4) 23 Apr 2021 16:34:02

Generated On: 09 Jun 2021 17:04:12

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

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (3)

Data signed: (b) (4) 23 Apr 2021 16:34:02

Generated On: 09 Jun 2021 17:04:12

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

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (4)

Data signed: (b) (4) 23 Apr 2021 16:34:02

Generated On: 09 Jun 2021 17:04:12

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 05 Apr 2021

Form: Symptom Log (4)

Data signed: (b) (4) 23 Apr 2021 16:34:02

Generated On: 09 Jun 2021 17:04:12

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	01 APR 2021	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (4)

Data signed: (b) (4) 23 Apr 2021 16:34:02

Generated On: 09 Jun 2021 17:04:12

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

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (4)

Data signed: (b) (4) 23 Apr 2021 16:34:02

Generated On: 09 Jun 2021 17:04:12

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 ☐

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (5)

Data signed: (b) (4) 23 Apr 2021 16:34:02

Generated On: 09 Jun 2021 17:04:12

Symptom Day

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

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Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (5)

Data signed: (b) (4) 23 Apr 2021 16:34:02

Generated On: 09 Jun 2021 17:04:12

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	02 APR 2021	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (5)

Data signed: (b) (4) 23 Apr 2021 16:34:02

Generated On: 09 Jun 2021 17:04:12

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

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Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (5)

Data signed: (b) (4) 23 Apr 2021 16:34:02

Generated On: 09 Jun 2021 17:04:12

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 ☐

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (6)

Data signed: (b) (4) 23 Apr 2021 16:34:02

Generated On: 09 Jun 2021 17:04:12

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"/>

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (6)

Data signed: (b) (4) 23 Apr 2021 16:34:02

Generated On: 09 Jun 2021 17:04:12

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

Date	03 APR 2021
------	-------------

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

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

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

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

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

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

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

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (6)

Data signed: (b) (4) 23 Apr 2021 16:34:02

Generated On: 09 Jun 2021 17:04:12

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

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (6)

Data signed: (b) (4) 23 Apr 2021 16:34:02

Generated On: 09 Jun 2021 17:04:12

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 ☐

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (7)

Data signed: (b) (4) 23 Apr 2021 16:34:02

Generated On: 09 Jun 2021 17:04:12

Symptom Day

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

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Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (7)

Data signed: (b) (4) 23 Apr 2021 16:34:02

Generated On: 09 Jun 2021 17:04:12

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	04 APR 2021	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (7)

Data signed: (b) (4) 23 Apr 2021 16:34:02

Generated On: 09 Jun 2021 17:04:12

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

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Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (7)

Data signed: (b) (4) 23 Apr 2021 16:34:02

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Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

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Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (8)

Data signed: (b) (4) 23 Apr 2021 16:34:02

Generated On: 09 Jun 2021 17:04:12

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 05 Apr 2021

Form: Symptom Log (8)

Data signed: (b) (4) 23 Apr 2021 16:34:02

Generated On: 09 Jun 2021 17:04:12

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	05 APR 2021	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (8)

Data signed: (b) (4) 23 Apr 2021 16:34:02

Generated On: 09 Jun 2021 17:04:12

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

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Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (8)

Data signed: (b) (4) 23 Apr 2021 16:34:02

Generated On: 09 Jun 2021 17:04:12

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

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Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (9)

Data signed: (b) (4) 23 Apr 2021 16:34:02

Generated On: 09 Jun 2021 17:04:12

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 05 Apr 2021

Form: Symptom Log (9)

Data signed: (b) (4) 23 Apr 2021 16:34:02

Generated On: 09 Jun 2021 17:04:12

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

Date	06 APR 2021
------	-------------

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

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

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

Temperature	96.4 F
-------------	--------

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

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

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

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

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Form: Symptom Log (9)

Data signed: (b) (4) 23 Apr 2021 16:34:02

Generated On: 09 Jun 2021 17:04:12

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

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Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (9)

Data signed: (b) (4) 23 Apr 2021 16:34:02

Generated On: 09 Jun 2021 17:04:12

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

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Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (10)

Data signed: (b) (4) 23 Apr 2021 16:34:02

Generated On: 09 Jun 2021 17:04:12

Symptom Day

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

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Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (10)

Data signed: (b) (4) 23 Apr 2021 16:34:02

Generated On: 09 Jun 2021 17:04:12

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	07 APR 2021	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	97.8 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (10)

Data signed: (b) (4) 23 Apr 2021 16:34:02

Generated On: 09 Jun 2021 17:04:12

	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 05 Apr 2021

Form: Symptom Log (10)

Data signed: (b) (4) 23 Apr 2021 16:34:02

Generated On: 09 Jun 2021 17:04:12

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

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Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (11)

Data signed: (b) (4) 23 Apr 2021 16:34:02

Generated On: 09 Jun 2021 17:04:12

Symptom Day

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

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Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (11)

Data signed: (b) (4) 23 Apr 2021 16:34:02

Generated On: 09 Jun 2021 17:04:12

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

Date	08 APR 2021
------	-------------

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

O2 Saturation	98 %
---------------	------

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

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

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

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Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (11)

Data signed: (b) (4) 23 Apr 2021 16:34:02

Generated On: 09 Jun 2021 17:04:12

	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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EAB) (1725)

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Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (11)

Data signed: (b) (4) 23 Apr 2021 16:34:02

Generated On: 09 Jun 2021 17:04:12

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 ☐

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (12)

Data signed: (b) (4) 23 Apr 2021 16:34:02

Generated On: 09 Jun 2021 17:04:12

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"/>

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (12)

Data signed: (b) (4) 23 Apr 2021 16:34:02

Generated On: 09 Jun 2021 17:04:12

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	09 APR 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 checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (12)

Data signed: (b) (4) 23 Apr 2021 16:34:02

Generated On: 09 Jun 2021 17:04:12

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (12)

Data signed: (b) (4) 23 Apr 2021 16:34:02

Generated On: 09 Jun 2021 17:04:12

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 ☐

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (13)

Data signed: (b) (4) 23 Apr 2021 16:34:02

Generated On: 09 Jun 2021 17:04:12

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"/>

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (13)

Data signed: (b) (4) 23 Apr 2021 16:34:02

Generated On: 09 Jun 2021 17:04:12

	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 APR 2021
------	-------------

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

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

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

Temperature	97.8 F
-------------	--------

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

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

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

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (13)

Data signed: (b) (4) 23 Apr 2021 16:34:02

Generated On: 09 Jun 2021 17:04:12

	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"/>

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (13)

Data signed: (b) (4) 23 Apr 2021 16:34:02

Generated On: 09 Jun 2021 17:04:12

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

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Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (14)

Data signed: (b) (4) 23 Apr 2021 16:34:02

Generated On: 09 Jun 2021 17:04:12

Symptom Day

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

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Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (14)

Data signed: (b) (4) 23 Apr 2021 16:34:02

Generated On: 09 Jun 2021 17:04:12

	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 APR 2021
------	-------------

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

O2 Saturation	98 %
---------------	------

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

Temperature	97.8 F
-------------	--------

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

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

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

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

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Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (14)

Data signed: (b) (4) 23 Apr 2021 16:34:02

Generated On: 09 Jun 2021 17:04:12

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (14)

Data signed: (b) (4) 23 Apr 2021 16:34:02

Generated On: 09 Jun 2021 17:04:12

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 ☐

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: COVID Diagnostic Test

Data signed: (b) (4) 23 Apr 2021 16:34:01

Generated On: 09 Jun 2021 17:04:12

Date of Visit	06 APR 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	06 APR 2021
Type of Test Performed	Nasopharyngeal Swab <input type="radio"/> Nasal Swab <input checked="" 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

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: COVID-19 Contact

Data signed: (b) (4) 26 Feb 2021 03:58:31

Generated On: 09 Jun 2021 17:04:12

Date of Contact	13 JAN 2021
Time of Contact	12:00
Date and Time of Contact (derived)	13 JAN 2021 12:00
Type of Contact	<div>Clinic Visit - Scheduled<input type="checkbox"/></div> <div>Clinical Visit - Unscheduled<input type="checkbox"/></div> <div>Safety Call<input checked="" type="checkbox"/></div> <div>Convalescent Tele-visit<input type="checkbox"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes<input checked="" type="checkbox"/></div> <div>No<input type="checkbox"/></div>

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (1)

Data signed: (b) (4) 26 Feb 2021 03:58:31

Generated On: 09 Jun 2021 17:04:12

Symptom Day

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

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (1)

Data signed: (b) (4) 26 Feb 2021 03:58:31

Generated On: 09 Jun 2021 17:04:12

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	11 JAN 2021	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (1)

Data signed: (b) (4) 26 Feb 2021 03:58:31

Generated On: 09 Jun 2021 17:04:12

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

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (1)

Data signed: (b) (4) 26 Feb 2021 03:58:31

Generated On: 09 Jun 2021 17:04:12

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

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (2)

Data signed: (b) (4) 26 Feb 2021 03:58:31

Generated On: 09 Jun 2021 17:04:12

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"/>

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (2)

Data signed: (b) (4) 26 Feb 2021 03:58:31

Generated On: 09 Jun 2021 17:04:12

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

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (2)

Data signed: (b) (4) 26 Feb 2021 03:58:31

Generated On: 09 Jun 2021 17:04:12

	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"/>

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (2)

Data signed: (b) (4) 26 Feb 2021 03:58:31

Generated On: 09 Jun 2021 17:04:12

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

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (3)

Data signed: (b) (4) 26 Feb 2021 03:58:31

Generated On: 09 Jun 2021 17:04:12

Symptom Day

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

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (3)

Data signed: (b) (4) 26 Feb 2021 03:58:31

Generated On: 09 Jun 2021 17:04:12

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

Date	13 JAN 2021
------	-------------

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

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

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

Temperature	96.6 F
-------------	--------

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

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

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

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

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (3)

Data signed: (b) (4) 26 Feb 2021 03:58:31

Generated On: 09 Jun 2021 17:04:12

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (3)

Data signed: (b) (4) 26 Feb 2021 03:58:31

Generated On: 09 Jun 2021 17:04:12

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

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (4)

Data signed: (b) (4) 26 Feb 2021 03:58:31

Generated On: 09 Jun 2021 17:04:12

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 13 Jan 2021

Form: Symptom Log (4)

Data signed: (b) (4) 26 Feb 2021 03:58:31

Generated On: 09 Jun 2021 17:04:12

	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	98 %
---------------	------

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

Temperature	97.9 F
-------------	--------

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

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

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

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

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EAB) (1725)

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (4)

Data signed: (b) (4) 26 Feb 2021 03:58:31

Generated On: 09 Jun 2021 17:04:12

	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 13 Jan 2021

Form: Symptom Log (4)

Data signed: (b) (4) 26 Feb 2021 03:58:31

Generated On: 09 Jun 2021 17:04:12

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

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (5)

Data signed: (b) (4) 26 Feb 2021 03:58:31

Generated On: 09 Jun 2021 17:04:12

Symptom Day

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

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (5)

Data signed: (b) (4) 26 Feb 2021 03:58:31

Generated On: 09 Jun 2021 17:04:12

	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	100 %
---------------	-------

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

Temperature	98.2 F
-------------	--------

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

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

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

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

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EAB) (1725)

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (5)

Data signed: (b) (4) 26 Feb 2021 03:58:31

Generated On: 09 Jun 2021 17:04:12

	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"/>

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (5)

Data signed: (b) (4) 26 Feb 2021 03:58:31

Generated On: 09 Jun 2021 17:04:12

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

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (6)

Data signed: (b) (4) 26 Feb 2021 03:58:31

Generated On: 09 Jun 2021 17:04:12

Symptom Day

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

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (6)

Data signed: (b) (4) 26 Feb 2021 03:58:31

Generated On: 09 Jun 2021 17:04:12

	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	100 %
---------------	-------

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

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

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (6)

Data signed: (b) (4) 26 Feb 2021 03:58:31

Generated On: 09 Jun 2021 17:04:12

	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 13 Jan 2021

Form: Symptom Log (6)

Data signed: (b) (4) 26 Feb 2021 03:58:31

Generated On: 09 Jun 2021 17:04:12

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

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (7)

Data signed: (b) (4) 26 Feb 2021 03:58:31

Generated On: 09 Jun 2021 17:04:12

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"/>

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (7)

Data signed: (b) (4) 26 Feb 2021 03:58:31

Generated On: 09 Jun 2021 17:04:12

	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 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (7)

Data signed: (b) (4) 26 Feb 2021 03:58:31

Generated On: 09 Jun 2021 17:04:12

	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 13 Jan 2021

Form: Symptom Log (7)

Data signed: (b) (4) 26 Feb 2021 03:58:31

Generated On: 09 Jun 2021 17:04:12

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

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (8)

Data signed: (b) (4) 26 Feb 2021 03:58:31

Generated On: 09 Jun 2021 17:04:12

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 13 Jan 2021

Form: Symptom Log (8)

Data signed: (b) (4) 26 Feb 2021 03:58:31

Generated On: 09 Jun 2021 17:04:12

	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	97.8 F
-------------	--------

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

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

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

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

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EAB) (1725)

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (8)

Data signed: (b) (4) 26 Feb 2021 03:58:31

Generated On: 09 Jun 2021 17:04:12

	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 13 Jan 2021

Form: Symptom Log (8)

Data signed: (b) (4) 26 Feb 2021 03:58:31

Generated On: 09 Jun 2021 17:04:12

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

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Folder: Covid-19 Assessment 13 Jan 2021

Form: COVID Diagnostic Test

Data signed: (b) (4) 26 Feb 2021 03:58:31

Generated On: 09 Jun 2021 17:04:12

Date of Visit	13 JAN 2021
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Date of Test	13 JAN 2021
Type of Test Performed	Nasopharyngeal Swab <input type="radio"/> Nasal Swab <input checked="" 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

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 23 Apr 2021 16:34:02

Generated On: 09 Jun 2021 17:04:12

[Generate Next COVID-19 Assessment](#)

Yes ☒

No ☐

US3322329

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 26 Feb 2021 03:58:31

Generated On: 09 Jun 2021 17:04:12

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	15 JAN 2021
Day 5	Yes	17 JAN 2021
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)	

US3322329

Folder: Illness Visit (2)

Form: Saliva Collection

Data signed: (b) (4) 23 Apr 2021 16:34:02

Generated On: 09 Jun 2021 17:04:12

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	08 APR 2021
Day 5	Yes	10 APR 2021
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)	

US3322329

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 26 Feb 2021 03:58:32

Generated On: 09 Jun 2021 17:04:12

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	13 JAN 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD1

US3322329

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 26 Feb 2021 03:58:32

Generated On: 09 Jun 2021 17:04:12

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	13 JAN 2021
Time of assessment (00:00-23:59)	14:08 (24 HR)
Vital Signs Date and Time (derived)	13 JAN 2021 14:08
Height (xxx.x)	73 in
Weight (xxx.x)	219 lb
Temperature (xxx.x)	96.6 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	61 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	117 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3322329

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Feb 2021 03:58:32

Generated On: 09 Jun 2021 17:04:12

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

13 JAN 2021

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

US3322329

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 26 Feb 2021 03:58:32

Generated On: 09 Jun 2021 17:04:12

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

13 JAN 2021

US3322329

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 23 Apr 2021 16:34:02

Generated On: 09 Jun 2021 17:04:12

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

Visit date (dd MMM yyyy)	06 APR 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	SICKD1
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US3322329

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 23 Apr 2021 16:34:02

Generated On: 09 Jun 2021 17:04:12

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	06 APR 2021
Time of assessment (00:00-23:59)	09:11 (24 HR)
Vital Signs Date and Time (derived)	06 APR 2021 09:11
Height (xxx.x)	73 in
Weight (xxx.x)	215 lb
Temperature (xxx.x)	96.4 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	60 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	141 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3322329

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Apr 2021 16:34:02

Generated On: 09 Jun 2021 17:04:12

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

06 APR 2021

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

US3322329

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 23 Apr 2021 16:34:02

Generated On: 09 Jun 2021 17:04:12

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

06 APR 2021

US3322329

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:04:12

Was this visit performed? Yes ☐
No ☐

Visit date (dd MMM yyyy) _____

Was visit performed at the participant's home or at the clinic? Home ☐
Clinic ☐

Folder OID _____

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Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:04:12

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

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Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:04:12

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.

US3322329

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 09 Jun 2021 17:04:12

Was Blood Sample Taken for Immunologic Assessment of	Yes	<input type="checkbox"/>
SARS_COV-2 Infection?	No	<input type="checkbox"/>
	NA (COVID-19 Negative)	<input type="checkbox"/>

Date of Collection	
--------------------	--

US3322329

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

Form: Visit Date

Data signed: (b) (4) 26 Feb 2021 03:58:32

Generated On: 09 Jun 2021 17:04:12

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

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

Folder OID	UNBLND_DECIDE
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US3322329

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

Form: Unblinding

Data signed: (b) (4) 24 Mar 2021 22:08:27

Generated On: 09 Jun 2021 17:04:12

Date of updated informed consent (dd MMM yyyy) 21 JAN 2021

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

Was the participant unblinded? Yes ☒ No ☐

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

Date of unblinding (dd MMM yyyy) 21 JAN 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

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

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

Will participant receive mRNA-1273? Yes ☐ No ☒

Placebo Only Flag _____
Continuing with mRNA-1273 _____

US3322329

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Feb 2021 03:58:32

Generated On: 09 Jun 2021 17:04:12

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	21 JAN 2021
Collection time (00:00-23:59)	13:42 (24 HR)
Collection date and time (derived)	21 JAN 2021 13:42

US3322329

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 26 Feb 2021 03:58:32

Generated On: 09 Jun 2021 17:04:12

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	21 JAN 2021
Collection time (00:00 - 23:59)	13:37
Collection Date and Time (derived)	21 JAN 2021 13:37

US3322329

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 26 Feb 2021 03:58:31

Generated On: 09 Jun 2021 17:04:12

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3322329

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 28 Apr 2021 16:20:35

Generated On: 09 Jun 2021 17:04:12

AEID	USA-US060-2020-MRNA-1273-P30 1000006
Adverse event	FACIAL SWELLING
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)	17 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	22 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 28 Apr 2021 16:20:35

Generated On: 09 Jun 2021 17:04:12

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	True
Relationship to investigational product	Not Related <input type="radio"/> Related <input checked="" 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 (1)

Data signed: (b) (4) 28 Apr 2021 16:20:35

Generated On: 09 Jun 2021 17:04:12

SAE TERM: FACIAL SWELLING;
INTENSITY: SEVERE;
CAUSALITY: CONSIDERED IP
RELATED GIVEN IT OCCURRED
ON DAY 3 OF OBSERVATION
PERIOD POST-VACCINATION.
THE PRIOR COSMETIC
PROCEDURE BELIEVED TO
HAVE BEEN A CONTRIBUTING
FACTOR BUT NOT THE CAUSE
SINCE THE PROCEDURE WAS
ALMOST 2 WEEKS BEFORE THE
FACIAL SWELLING. A SAFETY
CALL WAS MADE ON 20 OCT
2020 DUE TO PATIENT
REPORTING GRADE 3
INJECTION SITE SWELLING.
SUBJECT CONFIRMED
EXPERIENCING INJECTION SITE
SWELLING/HARDNESS
MEASURING 125MM ON DAY 3
WHICH CAME DOWN TO 55MM
BY DAY 4. SHE EXPERIENCED
MILD DELTOID TENDERNESS
BUT DID NOT HAVE ANY
TROUBLE MOVING THE
AFFECTED ARM. DURING THIS
SAFETY CALL, THE SUBJECT
REPORTED RECEIVING
MEDICAL ATTENTION ON 17
OCTOBER 2020 DUE TO FACIAL
SWELLING. PATIENT STATED
SHE GOT DERMAL FILLER
(VOLUMA -CROSSLINKED
HYALURONIC ACID) COSMETIC

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 28 Apr 2021 16:20:35

Generated On: 09 Jun 2021 17:04:12

INJECTIONS IN CHEEKS ON 02 OCT 2020 PRIOR TO RECEIVING SECOND IP. IT WAS A PLANNED PROCEDURE, AND SHE FORGOT TO MENTION IT WHEN SHE CAME ONSITE FOR HER SECOND VACCINE ON 15 OCT 2020. DURING HER VISIT 2, THE PHYSICAL EXAM WAS NORMAL INCLUDING SKIN. PATIENT STATED SHE DEVELOPED BILATERAL FACIAL SWELLING (LEFT GREATER THAN RIGHT) THE NIGHT OF 17 OCT 2020. SHE CONTACTED THE DOCTOR THAT DID THE COSMETIC PROCEDURE, AND SHE WAS PRESCRIBED PREDNISOLONE FOR 5 DAYS. SHE TOOK PREDNISOLONE 25MG ON 17 OCT 2020 AT 10 AM AND PREDNISOLONE 40MG DAILY THEREAFTER. ON 20 OCT 2020, THE FACIAL SWELLING WAS ALMOST COMPLETELY RESOLVED WITH ONLY MINIMAL SWELLING UNDER THE LEFT EYE. THE REASON SHE CALLED HER DOCTOR AND THE REASON FOR TREATMENT WITH PREDNISOLONE WAS THE FACIAL SWELLING NOT IP INJECTION SITE SWELLING. FACIAL SWELLING IS A

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 28 Apr 2021 16:20:35

Generated On: 09 Jun 2021 17:04:12

POTENTIAL SIDE-EFFECT OF
VOLUMA DERMAL FILLER
TOPICAL INJECTIONS, AND I
BELIEVE THE INJECTION OF
DERMAL FILLER WAS A
CONTRIBUTING FACTOR TO
THE PATIENT DEVELOPING
FACIAL SWELLING.

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)	

US3322329

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 28 Apr 2021 16:20:35

Generated On: 09 Jun 2021 17:04:12

AEID

Adverse event

LEFT ARM INJECTION SITE
SWELLING

Was this a medically-attended AE?

Yes ☐

No ☒

Was this a Solicited Adverse Reaction?

Yes ☒

No ☐

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

15 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

22 OCT 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 28 Apr 2021 16:20:35

Generated On: 09 Jun 2021 17:04:12

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 type="radio"/> Related <input checked="" 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	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

US3322329

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 28 Apr 2021 16:20:35

Generated On: 09 Jun 2021 17:04:12

AEID

Adverse event

LEFT ARM INJECTION SITE
TENDERNESS

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

17 NOV 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

01 DEC 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 28 Apr 2021 16:20:35

Generated On: 09 Jun 2021 17:04:12

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

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 28 Apr 2021 16:20:35

Generated On: 09 Jun 2021 17:04:12

AEID

Adverse event

UPPER RESPIRATORY
INFECTION

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

11 JAN 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

14 JAN 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 28 Apr 2021 16:20:35

Generated On: 09 Jun 2021 17:04:12

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

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 28 Apr 2021 16:20:35

Generated On: 09 Jun 2021 17:04:12

AEID	
Adverse event	UPPER RESPIRATORY 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)	29 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)	06 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 type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 28 Apr 2021 16:20:35

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

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 28 Apr 2021 16:20:35

Generated On: 09 Jun 2021 17:04:12

AEID

Adverse event

GENERALIZED MYALGIA

Was this a medically-attended AE?

Yes ☐

No ☒

Was this a Solicited Adverse Reaction?

Yes ☒

No ☐

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

16 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

19 SEP 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 28 Apr 2021 16:20:35

Generated On: 09 Jun 2021 17:04:12

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

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 26 Feb 2021 03:58:31

Generated On: 09 Jun 2021 17:04:12

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

Yes ☒

No ☐

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

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 23 Apr 2021 16:34:01

Generated On: 09 Jun 2021 17:04:12

Name of Medication NAPROXEN

Prophylaxis Yes ☐
No ☒

Indication GENERALIZED MYALGIA

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 23 Apr 2021 16:34:01

Generated On: 09 Jun 2021 17:04:12

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		16 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		16 SEP 2020
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 23 Apr 2021 16:34:01

Generated On: 09 Jun 2021 17:04:12

Name of Medication ESTRADIOL PELLET

Prophylaxis Yes ☐
No ☒

Indication POST MENOPAUSAL

Dose per administration 25

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

EVERY 3 MONTHS

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) 23 Apr 2021 16:34:01

Generated On: 09 Jun 2021 17:04:12

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2014	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 23 Apr 2021 16:34:01

Generated On: 09 Jun 2021 17:04:12

Name of Medication TESTOSTERONE PELLET

Prophylaxis Yes ☐
No ☒

Indication POST MENOPAUSAL

Dose per administration 87.5

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

EVERY 3 MONTHS

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 23 Apr 2021 16:34:01

Generated On: 09 Jun 2021 17:04:12

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2014	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 23 Apr 2021 16:34:01

Generated On: 09 Jun 2021 17:04:12

Name of Medication PREDNISOLONE

Prophylaxis Yes ☐
No ☒

Indication FACIAL SWELLING

Dose per administration 25

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) 23 Apr 2021 16:34:01

Generated On: 09 Jun 2021 17:04:12

	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)		17 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		17 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 23 Apr 2021 16:34:01

Generated On: 09 Jun 2021 17:04:12

Name of Medication PREDNISOLONE

Prophylaxis Yes ☐
No ☒

Indication FACIAL SWELLING

Dose per administration 40

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)

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 23 Apr 2021 16:34:01

Generated On: 09 Jun 2021 17:04:12

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

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 23 Apr 2021 16:34:01

Generated On: 09 Jun 2021 17:04:12

Name of Medication VOLUMA (CROSSLINKED
HYALURONIC ACID)

Prophylaxis Yes ☒
No ☐

Indication COSMETIC PROCEDURE

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 23 Apr 2021 16:34:01

Generated On: 09 Jun 2021 17:04:12

	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)	02 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	02 OCT 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 23 Apr 2021 16:34:01

Generated On: 09 Jun 2021 17:04:12

Name of Medication NAPROXEN

Prophylaxis Yes ☐
No ☒

Indication HEADACHE, LEFT ARM
INJECTION SITE SWELLING

Dose per administration 220

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 23 Apr 2021 16:34:01

Generated On: 09 Jun 2021 17:04:12

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	16 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		16 OCT 2020
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 23 Apr 2021 16:34:01

Generated On: 09 Jun 2021 17:04:12

Name of Medication AMOXICILLIN / CLAVULANIC ACID

Prophylaxis Yes ☐
No ☒

Indication FACIAL SWELLING

Dose per administration 875/125

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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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 23 Apr 2021 16:34:01

Generated On: 09 Jun 2021 17:04:12

	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)	17 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	21 NOV 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 23 Apr 2021 16:34:01

Generated On: 09 Jun 2021 17:04:12

Name of Medication BOTULINUM TOXIN (BOTOX)

Prophylaxis Yes ☒
No ☐

Indication FACIAL COSMETIC
INJECTION(WRINKLES)

Dose per administration 1

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

If dose unit is Other, specify INJECTION

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☒
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 23 Apr 2021 16:34:01

Generated On: 09 Jun 2021 17:04:12

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 23 Apr 2021 16:34:01

Generated On: 09 Jun 2021 17:04:12

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒
No ☐

Indication PREVENTATIVE HEALTHCARE

Dose per administration 1

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

If dose unit is Other, specify INJECTION

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 (10)

Data signed: (b) (4) 23 Apr 2021 16:34:01

Generated On: 09 Jun 2021 17:04:12

	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)		23 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		23 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 23 Apr 2021 16:34:01

Generated On: 09 Jun 2021 17:04:12

Name of Medication NAPROXEN

Prophylaxis Yes ☐
No ☒

Indication UPPER RESPIRATORY
INFECTION

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 23 Apr 2021 16:34:01

Generated On: 09 Jun 2021 17:04:12

	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)	29 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)	01 APR 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	3	
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 (12)

Data signed: (b) (4) 23 Apr 2021 16:34:01

Generated On: 09 Jun 2021 17:04:12

Name of Medication CEFDINIR

Prophylaxis Yes ☐
No ☒

Indication UPPER RESPIRATORY
INFECTION

Dose per administration 300

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 23 Apr 2021 16:34:01

Generated On: 09 Jun 2021 17:04:12

	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)	30 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)	08 APR 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3322329

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 26 Feb 2021 03:58:31

Generated On: 09 Jun 2021 17:04:12

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 26 Feb 2021 03:58:31

Generated On: 09 Jun 2021 17:04:12

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
02 OCT 2020	DERMAL FILLER INJECTION	Other	COSMETIC

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:04:12

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent
by participant, Protocol deviation, or Other, specify

US3322329

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:04:12

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 ☐

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Data signed: (b) (4) 26 Feb 2021 03:58:32

Generated On: 09 Jun 2021 17:04:12

SAEID	USA-US060-2020-MRNA-1273-P301000006
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	VERONICA
Investigator's Last Name	FRAGOSO
Site Address: Street	6550 MAPLERIDGE STREET
Site Address: City	HOUSTON
Site Address: State	TX
Site Address: Postal Code	77081
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form (1)

Data signed: (b) (4) 26 Feb 2021 03:58:32

Generated On: 09 Jun 2021 17:04:12

SAEID	USA-US060-2020-MRNA-1273-P301000006
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	VERONICA
Investigator's Last Name	FRAGOSO
Site Address: Street	6550 MAPLERIDGE STREET
Site Address: City	HOUSTON
Site Address: State	TX
Site Address: Postal Code	77081
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	22/OCT/2020 18:43
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

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form (2)

Data signed: (b) (4) 26 Feb 2021 03:58:32

Generated On: 09 Jun 2021 17:04:12

SAEID	USA-US060-2020-MRNA-1273-P301000006
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	VERONICA
Investigator's Last Name	FRAGOSO
Site Address: Street	6550 MAPLERIDGE STREET
Site Address: City	HOUSTON
Site Address: State	TX
Site Address: Postal Code	77081
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	02/NOV/2020 22:15
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

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form (3)

Data signed: (b) (4) 26 Feb 2021 03:58:32

Generated On: 09 Jun 2021 17:04:12

SAEID	USA-US060-2020-MRNA-1273-P301000006
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	VERONICA
Investigator's Last Name	FRAGOSO
Site Address: Street	6550 MAPLERIDGE STREET
Site Address: City	HOUSTON
Site Address: State	TX
Site Address: Postal Code	77081
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	03/NOV/2020 15:39
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

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form (4)

Data signed: (b) (4) 26 Feb 2021 03:58:32

Generated On: 09 Jun 2021 17:04:12

SAEID	USA-US060-2020-MRNA-1273-P301000006
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	VERONICA
Investigator's Last Name	FRAGOSO
Site Address: Street	6550 MAPLERIDGE STREET
Site Address: City	HOUSTON
Site Address: State	TX
Site Address: Postal Code	77081
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	09/NOV/2020 10:40
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

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form (5)

Data signed: (b) (4) 26 Feb 2021 03:58:32

Generated On: 09 Jun 2021 17:04:12

SAEID	USA-US060-2020-MRNA-1273-P301000006
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	VERONICA
Investigator's Last Name	FRAGOSO
Site Address: Street	6550 MAPLERIDGE STREET
Site Address: City	HOUSTON
Site Address: State	TX
Site Address: Postal Code	77081
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	16/NOV/2020 09:17
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

US3322329 (Prod: DM Clinical Research - Texas Center For Drug Development - ERN - PPDS)

US3322329

Form: Participant Creation

Generated On: 09 Jun 2021 17:04:12

[Participant ID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 14:53:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'US3322329'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	12 Sep 2020 15:14:27

US3322329

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:04:12

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:07:31
DataPoint Verified.		03 Mar 2021 21:27:41
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'Yes (Y)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 17:55:57

US3322329

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:04:12

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:07:31
DataPoint Verified.		03 Mar 2021 21:27:41
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered '12 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	12 Sep 2020 15:14:28

US3322329

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:04:12

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:07:31
DataPoint Verified.		03 Mar 2021 21:27:41
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'Clinic (Clinic)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 17:55:57

US3322329

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:04:12

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:07:31
User entered 'SCRN'	System	12 Sep 2020 17:55:57

US3322329

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:04:12

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:07:31
DataPoint Verified.		03 Mar 2021 21:27:55
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered (b) (6) 1968'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	12 Sep 2020 15:14:29

US3322329

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:04:12

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:07:31
DataPoint Verified.		03 Mar 2021 21:27:55
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered '51'	(b) (4) Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 17:56:31

US3322329

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:04:12

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:07:31
User entered 'YEARS'	System	12 Sep 2020 17:56:31

US3322329

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:04:12

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:07:31
User entered '51'	System	12 Sep 2020 17:03:22

US3322329

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:04:12

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:07:31
DataPoint Verified.		03 Mar 2021 21:27:55
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'Female (F)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 17:56:31

US3322329

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:04:12

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:07:31
DataPoint Verified.		03 Mar 2021 21:27:55
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 17:56:31

US3322329

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:04:12

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:07:31
DataPoint Verified.		03 Mar 2021 21:27:55
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'l'	(b) (4) Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 17:56:31

US3322329

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:04:12

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:07:31
DataPoint Verified.		03 Mar 2021 21:27:55
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered '0'	(b) (4) Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 17:56:31

US3322329

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:04:12

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:07:31
DataPoint Verified.		03 Mar 2021 21:27:55
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered '0'	(b) (4) Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 17:56:31

US3322329

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:04:12

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:07:31
DataPoint Verified.		03 Mar 2021 21:27:55
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered '0'	(b) (4) Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 17:56:31

US3322329

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:04:12

Native Hawaiian or other Pacific Islander

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:07:31
DataPoint Verified.		03 Mar 2021 21:27:55
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered '0'	(b) (4) Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 17:56:31

US3322329

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:04:12

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:07:31
DataPoint Verified.		03 Mar 2021 21:27:55
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered '0'	(b) (4) Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 17:56:31

US3322329

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:04:12

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:07:31
DataPoint Verified.		03 Mar 2021 21:27:55
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered empty.	(b) (4) Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 17:56:31

US3322329

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:04:12

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:07:31
DataPoint Verified.		03 Mar 2021 21:27:55
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered '0'	(b) (4) Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 17:56:31

US3322329

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:04:12

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:07:31
DataPoint Verified.		03 Mar 2021 21:27:55
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered '0'	(b) (4) Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 17:56:31

US3322329

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:04:12

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:07:31
DataPoint Verified.		03 Mar 2021 21:33:09
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered '12 Sep 2020'	(b) (4) Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 17:03:22

US3322329

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:04:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:07:31
User entered 'Sep 2020'	System	12 Sep 2020 17:03:22

US3322329

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:04:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:07:31
User entered '2020'	System	12 Sep 2020 17:03:22

US3322329

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:04:12

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:07:31
DataPoint Verified.		03 Mar 2021 21:33:09
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'Amendment 3 (3)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 17:03:22

US3322329

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:04:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:07:31
DataPoint Verified.		03 Mar 2021 21:33:09
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'Yes (Y)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 17:03:22

US3322329

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:04:12

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:07:31
DataPoint Verified.		03 Mar 2021 21:33:09
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered empty.	(b) (4) Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 17:03:22

US3322329

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:04:12

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:07:31
DataPoint Verified.		03 Mar 2021 21:33:09
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered empty.	(b) (4) Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 17:03:22

US3322329

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:04:12

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:07:31
DataPoint Verified.		03 Mar 2021 21:33:09
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'No (N)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 17:03:22

US3322329

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:04:12

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:07:31
DataPoint Verified.		03 Mar 2021 21:33:09
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	12 Sep 2020 15:14:28

US3322329

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:04:12

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:07:31
User entered 'I'	System	12 Sep 2020 17:03:36

US3322329

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 17:04:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:07:31
DataPoint Verified.		03 Mar 2021 21:30:14
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'Yes (Y)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 17:03:36

US3322329

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 17:04:12

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:07:31
DataPoint Verified.		03 Mar 2021 21:27:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'Yes (Y)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 17:58:36

US3322329

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:04:12

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:07:31
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:07:28
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Uterine therapeutic procedures, PT: Hysterectomy, LLT: Hysterectomy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Sep 2020 17:59:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Sep 2020 17:59:44
Data point term sent to Coder	System	12 Sep 2020 17:58:56
User entered 'Hysterectomy'	Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 17:58:54

US3322329

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:04:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:07:31
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:07:28
User entered 'UN UNK 2007'	Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 17:58:54

US3322329

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:04:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:07:31
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:07:28
User entered '0'	Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 17:58:54

US3322329

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:04:12

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:07:31
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:07:28
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 17:58:54

US3322329

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:04:12

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:07:31
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:07:28
User entered 'UN UNK 2007'	Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 17:58:54

US3322329

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:04:12

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:07:31
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:07:28
User entered '0'	Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 17:58:54

US3322329

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:04:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:07:31
User entered 'Jan 2007'	System	12 Sep 2020 17:58:54

US3322329

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:04:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:07:31
User entered '2007'	System	12 Sep 2020 17:58:54

US3322329

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:04:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:07:31
User entered 'Jan 2007'	System	12 Sep 2020 17:58:54

US3322329

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:04:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:07:31
User entered '2007'	System	12 Sep 2020 17:58:54

US3322329

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:04:12

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:07:31
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:07:28
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).		21 Oct 2020 16:56:55
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' answered with 'updated, please see line 4' (Site from DM).	Frances Saubon (b) (4) (b) (4)	20 Oct 2020 21:52:01
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 14:55:56
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Limb therapeutic procedures, PT: Foot operation, LLT: Foot surgery - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Sep 2020 18:00:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Sep 2020 18:00:45
Data point term sent to Coder	System	12 Sep 2020 17:59:58
User entered 'Foot surgery'	Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 17:59:09

US3322329

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:04:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:07:31
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:07:28
User entered 'UN UNK 2018'	Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 17:59:09

US3322329

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:04:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:07:31
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:07:28
User entered '0'	Elisa Moralez (b) (4)	12 Sep 2020 17:59:09

US3322329

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:04:12

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:07:31
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:07:28
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 17:59:09

US3322329

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:04:12

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:07:31
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:07:28
User entered 'UN UNK 2018'	Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 17:59:09

US3322329

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:04:12

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:07:31
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:07:28
User entered '0'	Elisa Moralez (b) (4)	12 Sep 2020 17:59:09

US3322329

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:04:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:07:31
User entered 'Jan 2018'	System	12 Sep 2020 17:59:09

US3322329

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:04:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:07:31
User entered '2018'	System	12 Sep 2020 17:59:09

US3322329

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:04:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:07:31
User entered 'Jan 2018'	System	12 Sep 2020 17:59:09

US3322329

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:04:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:07:31
User entered '2018'	System	12 Sep 2020 17:59:09

US3322329

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:04:12

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:07:31
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:07:28
User coded data point as SOC: Reproductive system and breast disorders, HLG: Cervix disorders (excl infections and inflammations), HLT: Cervix disorders NEC, PT: Cervical dysplasia, LLT: Cervical dysplasia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Oct 2020 20:12:21
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Oct 2020 20:12:21
Data point term sent to Coder	System	14 Oct 2020 20:11:39
User entered 'Cervical dysplasia'	Frances Saubon (b) (4) (b) (4)	14 Oct 2020 20:11:28

US3322329

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:04:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:07:31
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:07:28
User entered 'UN UNK 2007'	Frances Saubon (b) (4)	14 Oct 2020 20:11:28

US3322329

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:04:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:07:31
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:07:28
User entered '0'	Frances Saubon (b) (4) (b) (4)	14 Oct 2020 20:11:28

US3322329

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:04:12

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:07:31
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:07:28
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	14 Oct 2020 20:11:28

US3322329

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:04:12

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:07:31
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:07:28
User entered 'UN UNK 2007'	Frances Saubon (b) (4) (b) (4)	14 Oct 2020 20:11:28

US3322329

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:04:12

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:07:31
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:07:28
User entered '0'	Frances Saubon (b) (4) (b) (4)	14 Oct 2020 20:11:28

US3322329

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:04:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:07:31
User entered 'Jan 2007'	System	14 Oct 2020 20:11:28

US3322329

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:04:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:07:31
User entered '2007'	System	14 Oct 2020 20:11:28

US3322329

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:04:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:07:31
User entered 'Jan 2007'	System	14 Oct 2020 20:11:28

US3322329

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:04:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:07:31
User entered '2007'	System	14 Oct 2020 20:11:28

US3322329

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:04:12

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:07:31
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:07:28
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Non-site specific injuries NEC, PT: Sports injury, LLT: Sports injury - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Oct 2020 11:01:28
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Oct 2020 11:01:28
Data point term sent to Coder	System	20 Oct 2020 21:52:42
User entered 'Tennis injury-left Foot'	Frances Saubon (b) (4) (b) (4)	20 Oct 2020 21:51:49

US3322329

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:04:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:07:31
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:07:28
User entered 'UN UNK 2018'	Frances Saubon (b) (4) (b) (4)	20 Oct 2020 21:51:49

US3322329

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:04:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:07:31
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:07:28
User entered '0'	Frances Saubon (b) (4) (b) (4)	20 Oct 2020 21:51:49

US3322329

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:04:12

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:07:31
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:07:28
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	20 Oct 2020 21:51:49

US3322329

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:04:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:07:31
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:07:28
User entered 'UN UNK 2018'	Frances Saubon (b) (4) (b) (4)	20 Oct 2020 21:51:49

US3322329

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:04:12

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:07:31
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:07:28
User entered '0'	Frances Saubon (b) (4) (b) (4)	20 Oct 2020 21:51:49

US3322329

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:04:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:07:31
User entered 'Jan 2018'	System	20 Oct 2020 21:51:49

US3322329

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:04:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:07:31
User entered '2018'	System	20 Oct 2020 21:51:49

US3322329

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:04:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:07:31
User entered 'Jan 2018'	System	20 Oct 2020 21:51:49

US3322329

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:04:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:07:31
User entered '2018'	System	20 Oct 2020 21:51:49

US3322329

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:04:12

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:07:31
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User coded data point as SOC: Social circumstances, HLT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\\23.0.	Coder Import (b) (4)	05 Nov 2020 00:26:00
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Nov 2020 00:26:00
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:07:28
Data point term sent to Coder	System	02 Nov 2020 16:45:34
User entered 'post menopausal'	Elisa Moralez (b) (4)	02 Nov 2020 16:44:46

US3322329

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:04:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:07:31
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:07:28
User entered 'un UNK 2014'	Elisa Moralez (b) (4) (b) (4)	02 Nov 2020 16:44:46

US3322329

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:04:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:07:31
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:07:28
User entered '0'	Elisa Moralez (b) (4) (b) (4)	02 Nov 2020 16:44:46

US3322329

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:04:12

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:07:31
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:07:28
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	02 Nov 2020 16:44:46

US3322329

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:04:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:07:31
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:07:28
User entered empty.	Elisa Moralez (b) (4) (b) (4)	02 Nov 2020 16:44:46

US3322329

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:04:12

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:07:31
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:07:28
User entered '0'	Elisa Moralez (b) (4) (b) (4)	02 Nov 2020 16:44:46

US3322329

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:04:12

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:07:31
User entered 'Jan 2014'	System	02 Nov 2020 16:44:46

US3322329

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:04:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:07:31
User entered '2014'	System	02 Nov 2020 16:44:46

US3322329

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:04:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:07:31
User entered empty.	System	02 Nov 2020 16:44:46

US3322329

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:04:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:07:31
User entered empty.	System	02 Nov 2020 16:44:46

US3322329

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:04:12

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:07:31
DataPoint Verified.		03 Mar 2021 21:28:41
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'Yes (Y)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 17:59:36

US3322329

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:04:12

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:07:31
DataPoint Verified.		03 Mar 2021 21:28:41
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered '12 Sep 2020'	(b) (4) Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 17:59:36

US3322329

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:04:12

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:07:31
DataPoint Verified.		03 Mar 2021 21:28:41
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
Query 'Per CDM: Please confirm if time 10:15 is AM or PM. Thank you.' canceled (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Sep 2020 13:51:10
User opened query 'Per CDM: Please confirm if time 10:15 is AM or PM. Thank you.' (Site from DM).		24 Sep 2020 12:32:03
User entered '10:15'	Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 17:59:36

US3322329

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:04:12

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:07:31
User entered '12 Sep 2020 10:15'	System	12 Sep 2020 17:59:36

US3322329

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:04:12

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:07:31
DataPoint Verified.		03 Mar 2021 21:28:41
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered '73' in	(b) (4)	
	Elisa Moralez (b) (4)	12 Sep 2020 17:59:36
	(b) (4)	
DataPoint set to visible.	System	12 Sep 2020 17:03:36

US3322329

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:04:12

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:07:31
DataPoint Verified.		03 Mar 2021 21:28:41
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered '215.8' lb	(b) (4) Elisa Moralez (b) (4)	12 Sep 2020 17:59:36
DataPoint set to visible.	(b) (4) System	12 Sep 2020 17:03:36

US3322329

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:04:12

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:07:31
User entered '28.53091'	System	12 Sep 2020 17:59:36
DataPoint set to visible.	System	12 Sep 2020 17:03:36

US3322329

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:04:12

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:07:31
User entered 'kg/m2'	System	12 Sep 2020 17:59:36
DataPoint set to visible.	System	12 Sep 2020 17:03:36

US3322329

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:04:12

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:07:31
DataPoint Verified.		03 Mar 2021 21:28:41
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered missing code ND - Not Done.	(b) (4) Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 17:59:36

US3322329

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:04:12

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:07:31
DataPoint Verified.		03 Mar 2021 21:28:41
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'Other (Other)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 17:59:36

US3322329

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:04:12

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:07:31
DataPoint Verified.		03 Mar 2021 21:28:41
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered missing code ND - Not Done.	(b) (4) Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 17:59:36

US3322329

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:04:12

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:07:31
DataPoint Verified.		03 Mar 2021 21:28:41
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered missing code ND - Not Done.	(b) (4) Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 17:59:36

US3322329

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:04:12

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:07:31
User entered 'bpm'	System	12 Sep 2020 17:59:36

US3322329

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:04:12

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:07:31
DataPoint Verified.		03 Mar 2021 21:28:41
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered missing code ND - Not Done.	(b) (4) Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 17:59:36

US3322329

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:04:12

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:07:31
User entered 'breaths/min'	System	12 Sep 2020 17:59:36

US3322329

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:04:12

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:07:31
DataPoint Verified.		03 Mar 2021 21:28:41
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered missing code ND - Not Done.	(b) (4) Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 17:59:36

US3322329

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:04:12

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:07:31
User entered 'mmHg'	System	12 Sep 2020 17:59:36

US3322329

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:04:12

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:07:31
DataPoint Verified.		03 Mar 2021 21:28:41
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered missing code ND - Not Done.	(b) (4) Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 17:59:36

US3322329

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:04:12

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:07:31
User entered 'mmHg'	System	12 Sep 2020 17:59:36

US3322329

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:04:12

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:07:31

US3322329

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:04:12

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:07:31

US3322329

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:04:12

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:07:31
DataPoint Verified.		03 Mar 2021 21:29:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'Yes (Y)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 17:59:44

US3322329

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:04:12

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:07:31
DataPoint Verified.		03 Mar 2021 21:29:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered '12 Sep 2020'	(b) (4) Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 17:59:44

US3322329

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:04:12

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:07:31
DataPoint Verified.		03 Mar 2021 21:29:46
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered '12 Sep 2020'	(b) (4) Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 17:59:57

US3322329

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:04:12

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:07:31
DataPoint Verified.		03 Mar 2021 21:29:46
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'No (N)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 17:59:57

US3322329

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:04:12

If No, what is the reason?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:07:31
DataPoint Verified.		03 Mar 2021 21:29:46
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User closed query 'Per DM CLR: Note,If No, what is the reason?= Surgically sterile and HYSTERECTOMY is recorded in MH; however associated condition with this surgery is not recorded as an MH condition. Ensure associated condition is recorded. Review and update as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Oct 2020 09:47:14
Query 'Per DM CLR: Note,If No, what is the reason?= Surgically sterile and HYSTERECTOMY is recorded in MH; however associated condition with this surgery is not recorded as an MH condition. Ensure associated condition is recorded. Review and update as appropriate.' answered with 'please see updated medical history' (Site from DM).	Frances Saubon (b) (4) (b) (4)	14 Oct 2020 20:11:52
User opened query 'Per DM CLR: Note,If No, what is the reason?= Surgically sterile and HYSTERECTOMY is recorded in MH; however associated condition with this surgery is not recorded as an MH condition. Ensure associated condition is recorded. Review and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	09 Oct 2020 11:29:34
User entered 'Surgically sterile (SURGICALLY STERILE)'	Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 17:59:57

US3322329

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:04:12

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:07:31
DataPoint Verified.		03 Mar 2021 21:29:46
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered empty.	(b) (4) Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 17:59:57

US3322329

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:04:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:07:31
DataPoint Verified.		03 Mar 2021 21:29:46
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'UN UNK 2007'	(b) (4) Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 17:59:57

US3322329

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:04:12

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:07:31
DataPoint Verified.		03 Mar 2021 21:29:46
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered '0'	(b) (4) Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 17:59:57

US3322329

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:04:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:07:31
DataPoint Verified.		03 Mar 2021 21:29:46
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered empty.	(b) (4) Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 17:59:57

US3322329

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:04:12

Date of last menstruation unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:07:31
DataPoint Verified.		03 Mar 2021 21:29:46
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered '0'	(b) (4) Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 17:59:57

US3322329

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:04:12

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:07:31
DataPoint Verified.		03 Mar 2021 21:34:56
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'No (N)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 18:00:21

US3322329

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:04:12

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:07:31
DataPoint Verified.		03 Mar 2021 21:34:56
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'No (N)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 18:00:21

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:04:12

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)	30 Apr 2021 10:07:31
DataPoint Verified.		03 Mar 2021 21:34:56
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'No (N)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 18:00:21

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:04:12

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)	30 Apr 2021 10:07:31
DataPoint Verified.		03 Mar 2021 21:34:56
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'No (N)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 18:00:21

US3322329

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:04:12

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:07:31
DataPoint Verified.		03 Mar 2021 21:34:56
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'No (N)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 18:00:21

US3322329

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:04:12

[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)	30 Apr 2021 10:07:31
DataPoint Verified.		03 Mar 2021 21:34:56
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'No (N)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 18:00:21

US3322329

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:04:12

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)	30 Apr 2021 10:07:31
DataPoint Verified.		03 Mar 2021 21:34:56
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'No (N)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 18:00:21

US3322329

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:04:12

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)	30 Apr 2021 10:07:31
DataPoint Verified.		03 Mar 2021 21:34:56
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'No (N)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 18:00:21

US3322329

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:04:12

[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)	30 Apr 2021 10:07:31
DataPoint Verified.		03 Mar 2021 21:34:56
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'No (N)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 18:00:21

US3322329

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:04:12

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)	30 Apr 2021 10:07:31
DataPoint Verified.		03 Mar 2021 21:34:56
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'No (N)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 18:00:21

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:04:12

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)	30 Apr 2021 10:07:31
DataPoint Verified.		03 Mar 2021 21:34:56
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'Yes (Y)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 18:00:21

US3322329

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:04:12

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:07:31
DataPoint Verified.		03 Mar 2021 21:34:56
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'No (N)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 18:00:21

US3322329

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:04:12

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:07:31
DataPoint Verified.		03 Mar 2021 21:34:56
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered empty.	(b) (4) Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 18:00:21

US3322329

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:04:12

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:07:31
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered '0'	Elisa Moralez (b) (4)	12 Sep 2020 18:00:21

US3322329

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:04:12

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:07:31
DataPoint Verified.		03 Mar 2021 21:34:56
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered '0'	(b) (4) Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 18:00:21

US3322329

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:04:12

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)	30 Apr 2021 10:07:31
DataPoint Verified.		03 Mar 2021 21:34:56
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered '0'	(b) (4) Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 18:00:21

US3322329

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:04:12

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)	30 Apr 2021 10:07:31
DataPoint Verified.		03 Mar 2021 21:34:56
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered '0'	(b) (4) Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 18:00:21

US3322329

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:04:12

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)	30 Apr 2021 10:07:31
DataPoint Verified.		03 Mar 2021 21:34:56
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered '0'	(b) (4) Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 18:00:21

US3322329

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:04:12

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:07:31
DataPoint Verified.		03 Mar 2021 21:34:56
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'I'	(b) (4) Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 18:00:21

US3322329

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:04:12

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:07:31
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered '0'	Elisa Moralez (b) (4)	12 Sep 2020 18:00:21

US3322329

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:04:12

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:07:31
DataPoint Verified.		03 Mar 2021 21:34:56
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered empty.	(b) (4) Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 18:00:21

US3322329

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:04:12

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
DataPoint Verified.		15 Apr 2021 15:10:43
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'Yes (Y)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 18:00:42

US3322329

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:04:12

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
DataPoint Verified.		15 Apr 2021 15:10:43
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered '12 Sep 2020'	(b) (4) Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 18:00:42

US3322329

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:04:12

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
DataPoint Verified.		15 Apr 2021 15:10:43
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'Clinic (Clinic)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 18:00:42

US3322329

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:04:12

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
User entered 'VISIT1'	System	12 Sep 2020 18:00:42

US3322329

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:04:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
DataPoint Verified.		03 Mar 2021 21:31:00
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered '12 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	12 Sep 2020 16:24:19

US3322329

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:04:12

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
DataPoint Verified.		03 Mar 2021 21:31:00
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered '113720'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	12 Sep 2020 16:24:19

US3322329

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:04:12

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
DataPoint Verified.		03 Mar 2021 21:31:00
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	12 Sep 2020 16:24:19

US3322329

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:04:12

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)	24 Apr 2021 15:11:51
DataPoint Verified.		03 Mar 2021 21:31:00
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'No (N)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 18:01:36

US3322329

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:04:12

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)	24 Apr 2021 15:11:51
DataPoint Verified.		03 Mar 2021 21:31:00
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'No (N)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 18:01:36

US3322329

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:04:12

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
DataPoint Verified.		03 Mar 2021 21:31:00
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'No (N)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 18:01:36

US3322329

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:04:12

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
DataPoint Verified.		03 Mar 2021 21:31:00
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'No (N)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 18:01:36

US3322329

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:04:12

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
DataPoint Verified.		03 Mar 2021 21:31:00
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'No (N)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 18:01:36

US3322329

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:04:12

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
DataPoint Verified.		03 Mar 2021 21:31:00
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'No (N)'	(b) (4) Elisa Moralez (b) (4)	23 Sep 2020 19:30:21
Amendment Manager: DataPoint set to visible.	(b) (4) System	19 Sep 2020 09:05:39
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 09:05:38

US3322329

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:04:12

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
DataPoint Verified.		03 Mar 2021 21:38:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered missing code ND - Not Done.	(b) (4) Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 18:02:43

US3322329

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:04:12

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
DataPoint Verified.		03 Mar 2021 21:38:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered missing code ND - Not Done.	(b) (4) Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 18:02:43

US3322329

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:04:12

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
DataPoint Verified.		03 Mar 2021 21:38:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered missing code ND - Not Done.	(b) (4) Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 18:02:43

US3322329

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:04:12

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
DataPoint Verified.		03 Mar 2021 21:38:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered missing code ND - Not Done.	(b) (4) Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 18:02:43

US3322329

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:04:12

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
User accepted default value 'Pre-Dose (PREDOSE)'	Elisa Morales (b) (4) (b) (4)	12 Sep 2020 18:02:43

US3322329

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:04:12

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
DataPoint Verified.		03 Mar 2021 21:38:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'Yes (Y)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 18:02:43

US3322329

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:04:12

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
DataPoint Verified.		03 Mar 2021 21:38:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered '12 Sep 2020'	(b) (4) Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 18:02:43

US3322329

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:04:12

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
DataPoint Verified.		03 Mar 2021 21:38:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered '10:30'	(b) (4) Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 18:02:43

US3322329

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:04:12

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
User entered '12 Sep 2020 10:30'	System	12 Sep 2020 18:02:43

US3322329

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:04:12

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
DataPoint Verified.		03 Mar 2021 21:38:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered '98.4' F	(b) (4) Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 18:02:43

US3322329

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:04:12

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
DataPoint Verified.		03 Mar 2021 21:38:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'Oral (Oral)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 18:02:43

US3322329

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:04:12

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
DataPoint Verified.		03 Mar 2021 21:38:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered empty.	(b) (4) Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 18:02:43

US3322329

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:04:12

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
DataPoint Verified.		03 Mar 2021 21:38:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered '62'	(b) (4) Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 18:02:43

US3322329

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:04:12

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
User entered 'bpm'	System	12 Sep 2020 18:02:43

US3322329

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:04:12

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
DataPoint Verified.		03 Mar 2021 21:38:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered '14'	(b) (4) Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 18:02:43

US3322329

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:04:12

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
User entered 'breaths/min'	System	12 Sep 2020 18:02:43

US3322329

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:04:12

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
DataPoint Verified.		03 Mar 2021 21:38:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered '121'	(b) (4) Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 18:02:43

US3322329

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:04:12

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
User entered 'mmHg'	System	12 Sep 2020 18:02:43

US3322329

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:04:12

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
DataPoint Verified.		03 Mar 2021 21:38:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered '76'	(b) (4) Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 18:02:43

US3322329

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:04:12

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
User entered 'mmHg'	System	12 Sep 2020 18:02:43

US3322329

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:04:12

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
DataPoint Verified.		03 Mar 2021 21:38:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered missing code ND - Not Done.	(b) (4) Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 18:02:43

US3322329

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:04:12

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
DataPoint Verified.		03 Mar 2021 21:38:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered missing code ND - Not Done.	(b) (4) Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 18:02:43

US3322329

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:04:12

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
User accepted default value 'Post-Dose (POSTDOSE)'	Elisa Morales (b) (4) (b) (4)	12 Sep 2020 18:02:43

US3322329

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:04:12

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
DataPoint Verified.		03 Mar 2021 21:38:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'Yes (Y)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 18:02:43

US3322329

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:04:12

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
DataPoint Verified.		03 Mar 2021 21:38:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered '12 Sep 2020'	(b) (4) Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 18:02:43

US3322329

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:04:12

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
DataPoint Verified.		03 Mar 2021 21:38:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered '12:37'	(b) (4) Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 18:02:43

US3322329

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:04:12

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
User entered '12 Sep 2020 12:37'	System	12 Sep 2020 18:02:43

US3322329

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:04:12

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
DataPoint Verified.		03 Mar 2021 21:38:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User closed query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3 Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4) (b) (4), (b) (6)	18 Sep 2020 06:55:26
Query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS' (Site from System).		17 Sep 2020 20:04:33
Amendment Manager: User opened query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	17 Sep 2020 00:34:05
User entered '94.8' F	Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 18:02:43

US3322329

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:04:12

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
DataPoint Verified.		03 Mar 2021 21:38:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'Oral (Oral)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 18:02:43

US3322329

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:04:12

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
DataPoint Verified.		03 Mar 2021 21:38:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered empty.	(b) (4) Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 18:02:43

US3322329

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:04:12

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
DataPoint Verified.		03 Mar 2021 21:38:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered '60'	(b) (4) Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 18:02:43

US3322329

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:04:12

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
User entered 'bpm'	System	12 Sep 2020 18:02:43

US3322329

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:04:12

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
DataPoint Verified.		03 Mar 2021 21:38:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered '14'	(b) (4) Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 18:02:43

US3322329

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:04:12

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
User entered 'breaths/min'	System	12 Sep 2020 18:02:43

US3322329

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:04:12

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
DataPoint Verified.		03 Mar 2021 21:38:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered '122'	(b) (4) Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 18:02:43

US3322329

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:04:12

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
User entered 'mmHg'	System	12 Sep 2020 18:02:43

US3322329

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:04:12

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
DataPoint Verified.		03 Mar 2021 21:38:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered '85'	(b) (4) Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 18:02:43

US3322329

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:04:12

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
User entered 'mmHg'	System	12 Sep 2020 18:02:43

US3322329

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:04:12

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
DataPoint Verified.		03 Mar 2021 21:38:37
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'No (N)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 18:02:47

US3322329

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:04:12

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
DataPoint Verified.		03 Mar 2021 21:38:37
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered empty.	(b) (4) Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 18:02:47

US3322329

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:04:12

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
DataPoint Verified.		03 Mar 2021 21:39:37
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'Yes (Y)'	(b) (4) Frances Saubon (b) (4) (b) (4)	12 Sep 2020 17:10:21

US3322329

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:04:12

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
DataPoint Verified.		03 Mar 2021 21:39:37
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered empty.	(b) (4) Frances Saubon (b) (4) (b) (4)	12 Sep 2020 17:10:21

US3322329

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:04:12

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)	24 Apr 2021 15:11:51
DataPoint Verified.		03 Mar 2021 21:39:37
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered empty.	(b) (4) Frances Saubon (b) (4) (b) (4)	12 Sep 2020 17:10:21

US3322329

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:04:12

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
User entered 'MRNA-1273 OR PLACEBO'	System	12 Sep 2020 17:10:21

US3322329

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:04:12

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
DataPoint Verified.		03 Mar 2021 21:39:37
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered '12 Sep 2020'	(b) (4) Frances Saubon (b) (4) (b) (4)	12 Sep 2020 17:10:21

US3322329

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:04:12

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
DataPoint Verified.		03 Mar 2021 21:39:37
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered '12:07'	(b) (4) Frances Saubon (b) (4) (b) (4)	12 Sep 2020 17:10:21

US3322329

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:04:12

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
User entered '12 Sep 2020 12:07'	System	12 Sep 2020 17:10:21

US3322329

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:04:12

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
DataPoint Verified.		03 Mar 2021 21:39:37
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'Left Arm (LEFT ARM)'	(b) (4) Frances Saubon (b) (4) (b) (4)	12 Sep 2020 17:10:21

US3322329

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:04:12

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
DataPoint Verified.		03 Mar 2021 21:39:37
User entered 'ONCE'	System	12 Sep 2020 17:10:21

US3322329

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:04:12

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
User entered 'INTRAMUSCULAR'	System	12 Sep 2020 17:10:21

US3322329

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:04:12

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
DataPoint Verified.		03 Mar 2021 21:40:37
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'Yes (Y)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 18:02:57

US3322329

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:04:12

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
DataPoint Verified.		03 Mar 2021 21:40:37
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered '12 Sep 2020'	(b) (4) Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 18:02:57

US3322329

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:04:12

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
DataPoint Verified.		03 Mar 2021 21:40:37
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered '11:40'	(b) (4) Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 18:02:57

US3322329

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:04:12

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
User entered '12 Sep 2020 11:40'	System	12 Sep 2020 18:02:57

US3322329

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:04:12

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
DataPoint Verified.		03 Mar 2021 21:40:46
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered '12 Sep 2020'	(b) (4) Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 18:03:05

US3322329

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:04:12

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Elisa Morales (b) (4) (b) (4)	12 Sep 2020 18:03:05

US3322329

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:04:12

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
DataPoint Verified.		03 Mar 2021 21:40:46
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'Yes (Y)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 18:03:05

US3322329

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:04:12

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
DataPoint Verified.		03 Mar 2021 21:40:46
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered '11:35'	(b) (4) Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 18:03:05

US3322329

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:04:12

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
User entered '12 Sep 2020 11:35'	System	12 Sep 2020 18:03:05

US3322329

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:04:12

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Elisa Morales (b) (4) (b) (4)	12 Sep 2020 18:03:05

US3322329

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:04:12

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
DataPoint Verified.		03 Mar 2021 21:40:46
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'No (N)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 18:03:05

US3322329

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:04:12

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
DataPoint Verified.		03 Mar 2021 21:40:46
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered empty.	(b) (4) Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 18:03:05

US3322329

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:04:12

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
User entered empty.	System	12 Sep 2020 18:03:05

US3322329

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:04:12

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
DataPoint Verified.		03 Mar 2021 21:40:52
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'Yes (Y)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 18:03:08

US3322329

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:04:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
User entered 'I'	System	12 Sep 2020 18:03:08

US3322329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
Data entry locked.	System	12 Sep 2020 17:10:21
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	12 Sep 2020 17:10:21

US3322329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:04:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-12T12:47:22', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '777c4804-9c50-410d-b8c7-df5185ebf16f' User entered 'Yes (Y)'	System	12 Sep 2020 17:48:50
	System	12 Sep 2020 17:48:50

US3322329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:04:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-12T12:48:30', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '777c4804-9c50-410d-b8c7-df5185ebf16f' User entered '94.8'	System	12 Sep 2020 17:48:50
	System	12 Sep 2020 17:48:50

US3322329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:04:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-12T12:48:34', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '777c4804-9c50-410d-b8c7-df5185ebf16f' User entered 'No (N)'	System	12 Sep 2020 17:48:50
	System	12 Sep 2020 17:48:50

US3322329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:04:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-12T12:48:49', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '777c4804-9c50-410d-b8c7-df5185ebf16f' User entered '12 Sep 2020 12:48'	System	12 Sep 2020 17:48:50
	System	12 Sep 2020 17:48:50

US3322329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:04:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
User entered '12 Sep 2020 12:27'	System	12 Sep 2020 17:10:21

US3322329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:04:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
User entered '12 Sep 2020 14:57'	System	12 Sep 2020 17:10:21

US3322329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
Data entry locked.	System	12 Sep 2020 17:10:21
User entered 'Day 1, after vaccination (at home)'	System	12 Sep 2020 17:10:21

US3322329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:04:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-12T17:30:06', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '48d9f6be-e7ec-4ee8-919d-28c8001e2663' User entered 'Yes (Y)'	System	12 Sep 2020 22:31:57
	System	12 Sep 2020 22:31:57

US3322329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:04:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-12T17:31:31', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '48d9f6be-e7ec-4ee8-919d-28c8001e2663' User entered '98.0'	System	12 Sep 2020 22:31:57
	System	12 Sep 2020 22:31:57

US3322329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:04:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-12T17:31:36', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '48d9f6be-e7ec-4ee8-919d-28c8001e2663'	System	12 Sep 2020 22:31:57
User entered 'No (N)'	System	12 Sep 2020 22:31:57

US3322329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:04:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-12T17:31:45', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '48d9f6be-e7ec-4ee8-919d-28c8001e2663' User entered '12 Sep 2020 17:31'	System	12 Sep 2020 22:31:57
	System	12 Sep 2020 22:31:57

US3322329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:04:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
User entered '12 Sep 2020 15:52'	System	12 Sep 2020 17:10:21

US3322329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:04:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
User entered '13 Sep 2020 11:59'	System	12 Sep 2020 17:10:21

US3322329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
Data entry locked.	System	12 Sep 2020 17:10:21
User entered 'Day 2'	System	12 Sep 2020 17:10:21

US3322329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:04:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-13T16:52:15', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '2f7c54b2-c80c-47f8-a7fd-0d92e59655d1' User entered 'Yes (Y)'	System	13 Sep 2020 21:52:46
	System	13 Sep 2020 21:52:46

US3322329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:04:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-13T16:52:21', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '2f7c54b2-c80c-47f8-a7fd-0d92e59655d1' User entered '97.3'	System	13 Sep 2020 21:52:46
	System	13 Sep 2020 21:52:46

US3322329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:04:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-13T16:52:38', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '2f7c54b2-c80c-47f8-a7fd-0d92e59655d1'	System	13 Sep 2020 21:52:46
User entered 'No (N)'	System	13 Sep 2020 21:52:46

US3322329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:04:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-13T16:52:44', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '2f7c54b2-c80c-47f8-a7fd-0d92e59655d1' User entered '13 Sep 2020 16:52'	System	13 Sep 2020 21:52:46
	System	13 Sep 2020 21:52:46

US3322329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:04:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
User entered '13 Sep 2020 12:00'	System	12 Sep 2020 17:10:21

US3322329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:04:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
User entered '14 Sep 2020 11:59'	System	12 Sep 2020 17:10:21

US3322329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
Data entry locked.	System	12 Sep 2020 17:10:21
User entered 'Day 3'	System	12 Sep 2020 17:10:21

US3322329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:04:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-14T14:56:53', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '410f6419-0a2a-4aae-b0f6-2c142a6c5dd6' User entered 'Yes (Y)'	System	14 Sep 2020 19:57:09
	System	14 Sep 2020 19:57:09

US3322329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:04:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-14T14:56:57', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '410f6419-0a2a-4aae-b0f6-2c142a6c5dd6' User entered '97.5'	System	14 Sep 2020 19:57:09
	System	14 Sep 2020 19:57:09

US3322329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:04:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-14T14:57:00', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '410f6419-0a2a-4aae-b0f6-2c142a6c5dd6'	System	14 Sep 2020 19:57:09
User entered 'No (N)'	System	14 Sep 2020 19:57:09

US3322329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:04:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-14T14:57:05', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '410f6419-0a2a-4aae-b0f6-2c142a6c5dd6' User entered '14 Sep 2020 14:57'	System	14 Sep 2020 19:57:09
	System	14 Sep 2020 19:57:09

US3322329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:04:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
User entered '14 Sep 2020 12:00'	System	12 Sep 2020 17:10:21

US3322329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:04:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
User entered '15 Sep 2020 11:59'	System	12 Sep 2020 17:10:21

US3322329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
Data entry locked.	System	12 Sep 2020 17:10:21
User entered 'Day 4'	System	12 Sep 2020 17:10:21

US3322329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:04:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-15T15:24:01', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'b6e51b65-716b-44f3-a61e-64d3af349b64' User entered 'Yes (Y)'	System	15 Sep 2020 20:24:49
	System	15 Sep 2020 20:24:49

US3322329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:04:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-15T15:24:05', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'b6e51b65-716b-44f3-a61e-64d3af349b64' User entered '97.5'	System	15 Sep 2020 20:24:49
	System	15 Sep 2020 20:24:49

US3322329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:04:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-15T15:24:08', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'b6e51b65-716b-44f3-a61e-64d3af349b64'	System	15 Sep 2020 20:24:49
User entered 'No (N)'	System	15 Sep 2020 20:24:49

US3322329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:04:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-15T15:24:15', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'b6e51b65-716b-44f3-a61e-64d3af349b64' User entered '15 Sep 2020 15:24'	System	15 Sep 2020 20:24:49
	System	15 Sep 2020 20:24:49

US3322329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:04:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
User entered '15 Sep 2020 12:00'	System	12 Sep 2020 17:10:21

US3322329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:04:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
User entered '16 Sep 2020 11:59'	System	12 Sep 2020 17:10:21

US3322329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
Data entry locked.	System	12 Sep 2020 17:10:21
User entered 'Day 5'	System	12 Sep 2020 17:10:21

US3322329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:04:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-16T21:17:35', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'ee541394-747f-4ad9-b488-7f1ca6d86ca1' User entered 'Yes (Y)'	System	17 Sep 2020 02:18:07
	System	17 Sep 2020 02:18:07

US3322329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:04:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-16T21:17:41', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'ee541394-747f-4ad9-b488-7f1ca6d86ca1' User entered '98.0'	System	17 Sep 2020 02:18:07
	System	17 Sep 2020 02:18:07

US3322329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:04:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-16T21:17:50', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'ee541394-747f-4ad9-b488-7f1ca6d86ca1' User entered 'Yes (Y)'	System	17 Sep 2020 02:18:07
	System	17 Sep 2020 02:18:07

US3322329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:04:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Participant took medication to treat muscle pain after exercise. ' (Site from System).		18 Sep 2020 08:44:13
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	17 Sep 2020 02:18:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-16T21:17:56', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'ee541394-747f-4ad9-b488-7f1ca6d86ca1'	System	17 Sep 2020 02:18:07
User entered '1'	System	17 Sep 2020 02:18:07

US3322329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:04:12

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-16T21:17:56', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'ee541394-747f-4ad9-b488-7f1ca6d86ca1' User entered '0'	System	17 Sep 2020 02:18:07
	System	17 Sep 2020 02:18:07

US3322329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:04:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-16T21:18:04', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'ee541394-747f-4ad9-b488-7f1ca6d86ca1' User entered '16 Sep 2020 21:18'	System	17 Sep 2020 02:18:07
	System	17 Sep 2020 02:18:07

US3322329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:04:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
User entered '16 Sep 2020 12:00'	System	12 Sep 2020 17:10:21

US3322329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:04:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
User entered '17 Sep 2020 11:59'	System	12 Sep 2020 17:10:21

US3322329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
Data entry locked.	System	12 Sep 2020 17:10:21
User entered 'Day 6'	System	12 Sep 2020 17:10:21

US3322329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:04:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-18T09:44:18', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '5de159f6-e24b-42a6-95a4-68ed3c706e8a' User entered 'Yes (Y)'	System	18 Sep 2020 14:44:36
	System	18 Sep 2020 14:44:36

US3322329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:04:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-18T09:44:23', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '5de159f6-e24b-42a6-95a4-68ed3c706e8a' User entered '97.3'	System	18 Sep 2020 14:44:36
	System	18 Sep 2020 14:44:36

US3322329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:04:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-18T09:44:29', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '5de159f6-e24b-42a6-95a4-68ed3c706e8a' User entered 'No (N)'	System	18 Sep 2020 14:44:36
	System	18 Sep 2020 14:44:36

US3322329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:04:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-18T09:44:33', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '5de159f6-e24b-42a6-95a4-68ed3c706e8a' User entered '18 Sep 2020 09:44'	System	18 Sep 2020 14:44:36
	System	18 Sep 2020 14:44:36

US3322329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:04:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
User entered '17 Sep 2020 12:00'	System	12 Sep 2020 17:10:21

US3322329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:04:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
User entered '18 Sep 2020 11:59'	System	12 Sep 2020 17:10:21

US3322329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
Data entry locked.	System	12 Sep 2020 17:10:21
User entered 'Day 7'	System	12 Sep 2020 17:10:21

US3322329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:04:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-19T07:28:02', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '8115fcba-c748-4921-a4e1-fb38b065799b' User entered 'Yes (Y)'	System	19 Sep 2020 12:28:20
	System	19 Sep 2020 12:28:20

US3322329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:04:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-19T07:28:09', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '8115fcba-c748-4921-a4e1-fb38b065799b' User entered '97.6'	System	19 Sep 2020 12:28:20
	System	19 Sep 2020 12:28:20

US3322329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:04:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-19T07:28:13', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '8115fcba-c748-4921-a4e1-fb38b065799b' User entered 'No (N)'	System	19 Sep 2020 12:28:20
	System	19 Sep 2020 12:28:20

US3322329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:04:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-19T07:28:17', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '8115fcba-c748-4921-a4e1-fb38b065799b' User entered '19 Sep 2020 07:28'	System	19 Sep 2020 12:28:20
	System	19 Sep 2020 12:28:20

US3322329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:04:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
User entered '18 Sep 2020 12:00'	System	12 Sep 2020 17:10:21

US3322329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:04:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
User entered '19 Sep 2020 11:59'	System	12 Sep 2020 17:10:21

US3322329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
Data entry locked.	System	12 Sep 2020 17:10:21
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	12 Sep 2020 17:10:21

US3322329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:04:12

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 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-12T12:49:47', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '03943e6f-2b15-4284-aaed-40680ab32f6a'	System	12 Sep 2020 17:50:12
User entered 'Does not interfere with activity (2)'	System	12 Sep 2020 17:50:12

US3322329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:04:12

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-12T12:49:54', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '03943e6f-2b15-4284-aaed-40680ab32f6a' User entered 'No (N)'	System	12 Sep 2020 17:50:12
	System	12 Sep 2020 17:50:12

US3322329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:04:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-12T12:50:01', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '03943e6f-2b15-4284-aaed-40680ab32f6a' User entered 'No (N)'	System	12 Sep 2020 17:50:12
	System	12 Sep 2020 17:50:12

US3322329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:04:12

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 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-12T12:50:05', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '03943e6f-2b15-4284-aaed-40680ab32f6a' User entered 'None (1)'	System	12 Sep 2020 17:50:12
	System	12 Sep 2020 17:50:12

US3322329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:04:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-12T12:50:09', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '03943e6f-2b15-4284-aaed-40680ab32f6a' User entered '12 Sep 2020 12:50'	System	12 Sep 2020 17:50:12
	System	12 Sep 2020 17:50:12

US3322329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:04:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
User entered '12 Sep 2020 12:27'	System	12 Sep 2020 17:10:21

US3322329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:04:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
User entered '12 Sep 2020 14:57'	System	12 Sep 2020 17:10:21

US3322329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
Data entry locked.	System	12 Sep 2020 17:10:21
User entered 'Day 1, after vaccination (at home)'	System	12 Sep 2020 17:10:21

US3322329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:04:12

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 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-12T17:31:59', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'de660c33-4a56-4409-8c75-53b700492ace'	System	12 Sep 2020 22:32:28
User entered 'Does not interfere with activity (2)'	System	12 Sep 2020 22:32:28

US3322329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:04:12

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-12T17:32:02', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'de660c33-4a56-4409-8c75-53b700492ace' User entered 'No (N)'	System	12 Sep 2020 22:32:28
	System	12 Sep 2020 22:32:28

US3322329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:04:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-12T17:32:15', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'de660c33-4a56-4409-8c75-53b700492ace' User entered 'No (N)'	System	12 Sep 2020 22:32:28
	System	12 Sep 2020 22:32:28

US3322329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:04:12

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 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-12T17:32:20', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'de660c33-4a56-4409-8c75-53b700492ace' User entered 'None (1)'	System	12 Sep 2020 22:32:28
	System	12 Sep 2020 22:32:28

US3322329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:04:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-12T17:32:24', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'de660c33-4a56-4409-8c75-53b700492ace' User entered '12 Sep 2020 17:32'	System	12 Sep 2020 22:32:28
	System	12 Sep 2020 22:32:28

US3322329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:04:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
User entered '12 Sep 2020 15:52'	System	12 Sep 2020 17:10:21

US3322329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:04:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
User entered '13 Sep 2020 11:59'	System	12 Sep 2020 17:10:21

US3322329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
Data entry locked.	System	12 Sep 2020 17:10:21
User entered 'Day 2'	System	12 Sep 2020 17:10:21

US3322329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:04:12

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 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-13T16:54:25', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '7b9bf29a-1d41-4e8e-bf63-159b7beb461a'	System	13 Sep 2020 21:57:16
User entered 'Does not interfere with activity (2)'	System	13 Sep 2020 21:57:16

US3322329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:04:12

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-13T16:54:29', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '7b9bf29a-1d41-4e8e-bf63-159b7beb461a' User entered 'No (N)'	System	13 Sep 2020 21:57:16
	System	13 Sep 2020 21:57:16

US3322329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:04:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-13T16:54:34', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '7b9bf29a-1d41-4e8e-bf63-159b7beb461a' User entered 'Yes (Y)'	System	13 Sep 2020 21:57:16
	System	13 Sep 2020 21:57:16

US3322329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:04:12

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-13T16:57:09', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '7b9bf29a-1d41-4e8e-bf63-159b7beb461a' User entered '20'	System	13 Sep 2020 21:57:16
	System	13 Sep 2020 21:57:16

US3322329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:04:12

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 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-13T16:56:44', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '7b9bf29a-1d41-4e8e-bf63-159b7beb461a' User entered 'None (1)'	System	13 Sep 2020 21:57:16
	System	13 Sep 2020 21:57:16

US3322329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:04:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-13T16:57:13', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '7b9bf29a-1d41-4e8e-bf63-159b7beb461a' User entered '13 Sep 2020 16:57'	System	13 Sep 2020 21:57:16
	System	13 Sep 2020 21:57:16

US3322329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:04:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
User entered '13 Sep 2020 12:00'	System	12 Sep 2020 17:10:21

US3322329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:04:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
User entered '14 Sep 2020 11:59'	System	12 Sep 2020 17:10:21

US3322329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
Data entry locked.	System	12 Sep 2020 17:10:21
User entered 'Day 3'	System	12 Sep 2020 17:10:21

US3322329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:04:12

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 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-14T14:57:12', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'e4a53382-dd0c-432f-b066-63d52055707c'	System	14 Sep 2020 19:57:54
User entered 'Does not interfere with activity (2)'	System	14 Sep 2020 19:57:54

US3322329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:04:12

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-14T14:57:14', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'e4a53382-dd0c-432f-b066-63d52055707c' User entered 'No (N)'	System	14 Sep 2020 19:57:54
	System	14 Sep 2020 19:57:54

US3322329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:04:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-14T14:57:36', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'e4a53382-dd0c-432f-b066-63d52055707c' User entered 'Yes (Y)'	System	14 Sep 2020 19:57:54
	System	14 Sep 2020 19:57:54

US3322329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:04:12

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-14T14:57:45', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'e4a53382-dd0c-432f-b066-63d52055707c' User entered '25'	System	14 Sep 2020 19:57:54
	System	14 Sep 2020 19:57:54

US3322329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:04:12

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 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-14T14:57:48', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'e4a53382-dd0c-432f-b066-63d52055707c' User entered 'None (1)'	System	14 Sep 2020 19:57:54
	System	14 Sep 2020 19:57:54

US3322329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:04:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-14T14:57:52', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'e4a53382-dd0c-432f-b066-63d52055707c' User entered '14 Sep 2020 14:57'	System	14 Sep 2020 19:57:54
	System	14 Sep 2020 19:57:54

US3322329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:04:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
User entered '14 Sep 2020 12:00'	System	12 Sep 2020 17:10:21

US3322329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:04:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
User entered '15 Sep 2020 11:59'	System	12 Sep 2020 17:10:21

US3322329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
Data entry locked.	System	12 Sep 2020 17:10:21
User entered 'Day 4'	System	12 Sep 2020 17:10:21

US3322329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:04:12

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 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-15T15:40:12', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '947df295-442e-40b8-bef0-3a9869ef2464'	System	15 Sep 2020 20:40:27
User entered 'Does not interfere with activity (2)'	System	15 Sep 2020 20:40:27

US3322329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:04:12

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-15T15:40:14', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '947df295-442e-40b8-bef0-3a9869ef2464'	System	15 Sep 2020 20:40:27
User entered 'No (N)'	System	15 Sep 2020 20:40:27

US3322329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:04:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-15T15:40:17', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '947df295-442e-40b8-bef0-3a9869ef2464' User entered 'No (N)'	System	15 Sep 2020 20:40:27
	System	15 Sep 2020 20:40:27

US3322329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:04:12

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 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-15T15:40:20', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '947df295-442e-40b8-bef0-3a9869ef2464'	System	15 Sep 2020 20:40:27
User entered 'None (1)'	System	15 Sep 2020 20:40:27

US3322329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:04:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-15T15:40:23', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '947df295-442e-40b8-bef0-3a9869ef2464'	System	15 Sep 2020 20:40:27
User entered '15 Sep 2020 15:40'	System	15 Sep 2020 20:40:27

US3322329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:04:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
User entered '15 Sep 2020 12:00'	System	12 Sep 2020 17:10:21

US3322329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:04:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
User entered '16 Sep 2020 11:59'	System	12 Sep 2020 17:10:21

US3322329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
Data entry locked.	System	12 Sep 2020 17:10:21
User entered 'Day 5'	System	12 Sep 2020 17:10:21

US3322329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:04:12

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 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-16T21:18:09', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '79586f86-0d92-4725-9c80-7d9715fb1987' User entered 'None (1)'	System	17 Sep 2020 02:18:41
	System	17 Sep 2020 02:18:41

US3322329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:04:12

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-16T21:18:13', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '79586f86-0d92-4725-9c80-7d9715fb1987'	System	17 Sep 2020 02:18:41
User entered 'No (N)'	System	17 Sep 2020 02:18:41

US3322329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:04:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-16T21:18:15', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '79586f86-0d92-4725-9c80-7d9715fb1987' User entered 'No (N)'	System	17 Sep 2020 02:18:41
	System	17 Sep 2020 02:18:41

US3322329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:04:12

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 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-16T21:18:19', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '79586f86-0d92-4725-9c80-7d9715fb1987' User entered 'None (1)'	System	17 Sep 2020 02:18:41
	System	17 Sep 2020 02:18:41

US3322329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:04:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-16T21:18:38', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '79586f86-0d92-4725-9c80-7d9715fb1987' User entered '16 Sep 2020 21:18'	System	17 Sep 2020 02:18:41
	System	17 Sep 2020 02:18:41

US3322329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:04:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
User entered '16 Sep 2020 12:00'	System	12 Sep 2020 17:10:21

US3322329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:04:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
User entered '17 Sep 2020 11:59'	System	12 Sep 2020 17:10:21

US3322329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
Data entry locked.	System	12 Sep 2020 17:10:21
User entered 'Day 6'	System	12 Sep 2020 17:10:21

US3322329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:04:12

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 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-18T09:44:39', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '7aa9ec87-7613-48b1-9554-c0820edbf2fa' User entered 'None (1)'	System	18 Sep 2020 14:44:58
	System	18 Sep 2020 14:44:58

US3322329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:04:12

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-18T09:44:42', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '7aa9ec87-7613-48b1-9554-c0820edbf2fa' User entered 'No (N)'	System	18 Sep 2020 14:44:58
	System	18 Sep 2020 14:44:58

US3322329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:04:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-18T09:44:45', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '7aa9ec87-7613-48b1-9554-c0820edbf2fa' User entered 'No (N)'	System	18 Sep 2020 14:44:58
	System	18 Sep 2020 14:44:58

US3322329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:04:12

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 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-18T09:44:50', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '7aa9ec87-7613-48b1-9554-c0820edbf2fa' User entered 'None (1)'	System	18 Sep 2020 14:44:58
	System	18 Sep 2020 14:44:58

US3322329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:04:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-18T09:44:54', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '7aa9ec87-7613-48b1-9554-c0820edbf2fa' User entered '18 Sep 2020 09:44'	System	18 Sep 2020 14:44:58
	System	18 Sep 2020 14:44:58

US3322329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:04:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
User entered '17 Sep 2020 12:00'	System	12 Sep 2020 17:10:21

US3322329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:04:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
User entered '18 Sep 2020 11:59'	System	12 Sep 2020 17:10:21

US3322329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
Data entry locked.	System	12 Sep 2020 17:10:21
User entered 'Day 7'	System	12 Sep 2020 17:10:21

US3322329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:04:12

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 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-19T07:28:21', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'a28ad5cd-58a6-460a-bcf9-6c134fd06fc0'	System	19 Sep 2020 12:28:45
User entered 'None (1)'	System	19 Sep 2020 12:28:45

US3322329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:04:12

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-19T07:28:28', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'a28ad5cd-58a6-460a-bcf9-6c134fd06fc0' User entered 'No (N)'	System	19 Sep 2020 12:28:45
	System	19 Sep 2020 12:28:45

US3322329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:04:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-19T07:28:32', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'a28ad5cd-58a6-460a-bcf9-6c134fd06fc0' User entered 'No (N)'	System	19 Sep 2020 12:28:45
	System	19 Sep 2020 12:28:45

US3322329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:04:12

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 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-19T07:28:35', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'a28ad5cd-58a6-460a-bcf9-6c134fd06fc0' User entered 'None (1)'	System	19 Sep 2020 12:28:45
	System	19 Sep 2020 12:28:45

US3322329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:04:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-19T07:28:43', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'a28ad5cd-58a6-460a-bcf9-6c134fd06fc0' User entered '19 Sep 2020 07:28'	System	19 Sep 2020 12:28:45
	System	19 Sep 2020 12:28:45

US3322329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:04:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
User entered '18 Sep 2020 12:00'	System	12 Sep 2020 17:10:21

US3322329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:04:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
User entered '19 Sep 2020 11:59'	System	12 Sep 2020 17:10:21

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
Data entry locked.	System	12 Sep 2020 17:10:21
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	12 Sep 2020 17:10:21

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:04:12

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-12T12:50:21', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'b1d5d57f-eabf-4b10-bd3b-f3f4928b7489' User entered 'None (0)'	System	12 Sep 2020 17:50:39
	System	12 Sep 2020 17:50:39

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:04:12

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-12T12:50:23', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'b1d5d57f-eabf-4b10-bd3b-f3f4928b7489' User entered 'None (0)'	System	12 Sep 2020 17:50:39
	System	12 Sep 2020 17:50:39

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:04:12

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-12T12:50:25', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'b1d5d57f-eabf-4b10-bd3b-f3f4928b7489' User entered 'None (0)'	System	12 Sep 2020 17:50:39
	System	12 Sep 2020 17:50:39

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:04:12

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-12T12:50:27', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'b1d5d57f-eabf-4b10-bd3b-f3f4928b7489' User entered 'None (0)'	System	12 Sep 2020 17:50:39
	System	12 Sep 2020 17:50:39

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:04:12

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-12T12:50:29', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'b1d5d57f-eabf-4b10-bd3b-f3f4928b7489' User entered 'None (0)'	System	12 Sep 2020 17:50:39
	System	12 Sep 2020 17:50:39

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:04:12

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-12T12:50:31', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'b1d5d57f-eabf-4b10-bd3b-f3f4928b7489' User entered 'None (0)'	System	12 Sep 2020 17:50:39
	System	12 Sep 2020 17:50:39

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:04:12

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 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-12T12:50:35', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'b1d5d57f-eabf-4b10-bd3b-f3f4928b7489' User entered 'No (N)'	System	12 Sep 2020 17:50:39
	System	12 Sep 2020 17:50:39

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:04:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-12T12:50:37', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'b1d5d57f-eabf-4b10-bd3b-f3f4928b7489'	System	12 Sep 2020 17:50:39
User entered '12 Sep 2020 12:50'	System	12 Sep 2020 17:50:39

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:04:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
User entered '12 Sep 2020 12:27'	System	12 Sep 2020 17:10:21

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:04:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
User entered '12 Sep 2020 14:57'	System	12 Sep 2020 17:10:21

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
Data entry locked.	System	12 Sep 2020 17:10:21
User entered 'Day 1, after vaccination (at home)'	System	12 Sep 2020 17:10:21

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:04:12

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-12T17:32:35', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'bc73e8d5-99c1-4709-91f3-cdc711db287d'	System	12 Sep 2020 22:33:12
User entered 'No interference with activity (1)'	System	12 Sep 2020 22:33:12

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:04:12

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-12T17:32:42', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'bc73e8d5-99c1-4709-91f3-cdc711db287d' User entered 'None (0)'	System	12 Sep 2020 22:33:12
	System	12 Sep 2020 22:33:12

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:04:12

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-12T17:32:46', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'bc73e8d5-99c1-4709-91f3-cdc711db287d' User entered 'None (0)'	System	12 Sep 2020 22:33:12
	System	12 Sep 2020 22:33:12

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:04:12

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-12T17:32:50', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'bc73e8d5-99c1-4709-91f3-cdc711db287d' User entered 'None (0)'	System	12 Sep 2020 22:33:12
	System	12 Sep 2020 22:33:12

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:04:12

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-12T17:32:55', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'bc73e8d5-99c1-4709-91f3-cdc711db287d' User entered 'None (0)'	System	12 Sep 2020 22:33:12
	System	12 Sep 2020 22:33:12

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:04:12

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-12T17:32:59', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'bc73e8d5-99c1-4709-91f3-cdc711db287d' User entered 'None (0)'	System	12 Sep 2020 22:33:12
	System	12 Sep 2020 22:33:12

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:04:12

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 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-12T17:33:05', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'bc73e8d5-99c1-4709-91f3-cdc711db287d' User entered 'No (N)'	System	12 Sep 2020 22:33:12
	System	12 Sep 2020 22:33:12

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:04:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-12T17:33:08', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'bc73e8d5-99c1-4709-91f3-cdc711db287d' User entered '12 Sep 2020 17:33'	System	12 Sep 2020 22:33:12
	System	12 Sep 2020 22:33:12

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:04:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
User entered '12 Sep 2020 15:52'	System	12 Sep 2020 17:10:21

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:04:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
User entered '13 Sep 2020 11:59'	System	12 Sep 2020 17:10:21

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
Data entry locked.	System	12 Sep 2020 17:10:21
User entered 'Day 2'	System	12 Sep 2020 17:10:21

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:04:12

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-13T16:57:20', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'f3131cc3-9f6e-48ee-821e-b0a5ba079bad' User entered 'None (0)'	System	13 Sep 2020 21:58:02
	System	13 Sep 2020 21:58:02

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:04:12

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-13T16:57:34', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'f3131cc3-9f6e-48ee-821e-b0a5ba079bad'	System	13 Sep 2020 21:58:02
User entered 'Some interference with activity (2)'	System	13 Sep 2020 21:58:02

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:04:12

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-13T16:57:40', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'f3131cc3-9f6e-48ee-821e-b0a5ba079bad' User entered 'None (0)'	System	13 Sep 2020 21:58:02
	System	13 Sep 2020 21:58:02

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:04:12

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-13T16:57:43', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'f3131cc3-9f6e-48ee-821e-b0a5ba079bad' User entered 'None (0)'	System	13 Sep 2020 21:58:02
	System	13 Sep 2020 21:58:02

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:04:12

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-13T16:57:46', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'f3131cc3-9f6e-48ee-821e-b0a5ba079bad' User entered 'None (0)'	System	13 Sep 2020 21:58:02
	System	13 Sep 2020 21:58:02

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:04:12

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-13T16:57:49', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'f3131cc3-9f6e-48ee-821e-b0a5ba079bad' User entered 'None (0)'	System	13 Sep 2020 21:58:02
	System	13 Sep 2020 21:58:02

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:04:12

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 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-13T16:57:55', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'f3131cc3-9f6e-48ee-821e-b0a5ba079bad' User entered 'No (N)'	System	13 Sep 2020 21:58:02
	System	13 Sep 2020 21:58:02

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:04:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-13T16:58:00', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'f3131cc3-9f6e-48ee-821e-b0a5ba079bad' User entered '13 Sep 2020 16:58'	System	13 Sep 2020 21:58:02
	System	13 Sep 2020 21:58:02

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:04:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
User entered '13 Sep 2020 12:00'	System	12 Sep 2020 17:10:21

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:04:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
User entered '14 Sep 2020 11:59'	System	12 Sep 2020 17:10:21

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
Data entry locked.	System	12 Sep 2020 17:10:21
User entered 'Day 3'	System	12 Sep 2020 17:10:21

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:04:12

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-14T14:57:57', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '7dcc9dbc-34a2-47dd-bc13-425d1337ed8e'	System	14 Sep 2020 19:58:22
User entered 'No interference with activity (1)'	System	14 Sep 2020 19:58:22

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:04:12

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-14T14:58:01', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '7dcc9dbc-34a2-47dd-bc13-425d1337ed8e' User entered 'None (0)'	System	14 Sep 2020 19:58:22
	System	14 Sep 2020 19:58:22

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:04:12

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-14T14:58:04', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '7dcc9dbc-34a2-47dd-bc13-425d1337ed8e' User entered 'None (0)'	System	14 Sep 2020 19:58:22
	System	14 Sep 2020 19:58:22

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:04:12

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-14T14:58:07', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '7dcc9dbc-34a2-47dd-bc13-425d1337ed8e' User entered 'None (0)'	System	14 Sep 2020 19:58:22
	System	14 Sep 2020 19:58:22

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:04:12

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-14T14:58:09', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '7dcc9dbc-34a2-47dd-bc13-425d1337ed8e' User entered 'None (0)'	System	14 Sep 2020 19:58:22
	System	14 Sep 2020 19:58:22

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:04:12

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-14T14:58:11', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '7dcc9dbc-34a2-47dd-bc13-425d1337ed8e' User entered 'None (0)'	System	14 Sep 2020 19:58:22
	System	14 Sep 2020 19:58:22

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:04:12

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 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-14T14:58:15', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '7dcc9dbc-34a2-47dd-bc13-425d1337ed8e' User entered 'No (N)'	System	14 Sep 2020 19:58:22
	System	14 Sep 2020 19:58:22

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:04:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-14T14:58:18', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '7dcc9dbc-34a2-47dd-bc13-425d1337ed8e' User entered '14 Sep 2020 14:58'	System	14 Sep 2020 19:58:22
	System	14 Sep 2020 19:58:22

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:04:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
User entered '14 Sep 2020 12:00'	System	12 Sep 2020 17:10:21

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:04:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
User entered '15 Sep 2020 11:59'	System	12 Sep 2020 17:10:21

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
Data entry locked.	System	12 Sep 2020 17:10:21
User entered 'Day 4'	System	12 Sep 2020 17:10:21

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:04:12

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-15T15:40:27', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '5998d42c-c86d-4e5b-bea9-c9862549e3e2' User entered 'None (0)'	System	15 Sep 2020 20:40:58
	System	15 Sep 2020 20:40:58

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:04:12

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-15T15:40:35', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '5998d42c-c86d-4e5b-bea9-c9862549e3e2'	System	15 Sep 2020 20:40:58
User entered 'No interference with activity (1)'	System	15 Sep 2020 20:40:58

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:04:12

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-15T15:40:39', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '5998d42c-c86d-4e5b-bea9-c9862549e3e2' User entered 'None (0)'	System	15 Sep 2020 20:40:58
	System	15 Sep 2020 20:40:58

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:04:12

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-15T15:40:42', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '5998d42c-c86d-4e5b-bea9-c9862549e3e2' User entered 'None (0)'	System	15 Sep 2020 20:40:58
	System	15 Sep 2020 20:40:58

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:04:12

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-15T15:40:44', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '5998d42c-c86d-4e5b-bea9-c9862549e3e2' User entered 'None (0)'	System	15 Sep 2020 20:40:58
	System	15 Sep 2020 20:40:58

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:04:12

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-15T15:40:47', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '5998d42c-c86d-4e5b-bea9-c9862549e3e2' User entered 'None (0)'	System	15 Sep 2020 20:40:58
	System	15 Sep 2020 20:40:58

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:04:12

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 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-15T15:40:50', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '5998d42c-c86d-4e5b-bea9-c9862549e3e2' User entered 'No (N)'	System	15 Sep 2020 20:40:58
	System	15 Sep 2020 20:40:58

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:04:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-15T15:40:52', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '5998d42c-c86d-4e5b-bea9-c9862549e3e2' User entered '15 Sep 2020 15:40'	System	15 Sep 2020 20:40:58
	System	15 Sep 2020 20:40:58

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:04:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
User entered '15 Sep 2020 12:00'	System	12 Sep 2020 17:10:21

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:04:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
User entered '16 Sep 2020 11:59'	System	12 Sep 2020 17:10:21

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
Data entry locked.	System	12 Sep 2020 17:10:21
User entered 'Day 5'	System	12 Sep 2020 17:10:21

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:04:12

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-16T21:26:04', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '74442301-b4be-4ab4-a60f-c33d06015118' User entered 'None (0)'	System	17 Sep 2020 02:26:33
	System	17 Sep 2020 02:26:33

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:04:12

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-16T21:26:06', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '74442301-b4be-4ab4-a60f-c33d06015118' User entered 'None (0)'	System	17 Sep 2020 02:26:33
	System	17 Sep 2020 02:26:33

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:04:12

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-16T21:26:14', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '74442301-b4be-4ab4-a60f-c33d06015118'	System	17 Sep 2020 02:26:33
User entered 'No interference with activity (1)'	System	17 Sep 2020 02:26:33

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:04:12

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-16T21:26:18', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '74442301-b4be-4ab4-a60f-c33d06015118' User entered 'None (0)'	System	17 Sep 2020 02:26:33
	System	17 Sep 2020 02:26:33

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:04:12

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-16T21:26:20', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '74442301-b4be-4ab4-a60f-c33d06015118' User entered 'None (0)'	System	17 Sep 2020 02:26:33
	System	17 Sep 2020 02:26:33

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:04:12

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-16T21:26:22', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '74442301-b4be-4ab4-a60f-c33d06015118' User entered 'None (0)'	System	17 Sep 2020 02:26:33
	System	17 Sep 2020 02:26:33

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:04:12

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 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-16T21:26:26', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '74442301-b4be-4ab4-a60f-c33d06015118' User entered 'No (N)'	System	17 Sep 2020 02:26:33
	System	17 Sep 2020 02:26:33

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:04:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-16T21:26:28', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '74442301-b4be-4ab4-a60f-c33d06015118' User entered '16 Sep 2020 21:26'	System	17 Sep 2020 02:26:33
	System	17 Sep 2020 02:26:33

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:04:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
User entered '16 Sep 2020 12:00'	System	12 Sep 2020 17:10:21

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:04:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
User entered '17 Sep 2020 11:59'	System	12 Sep 2020 17:10:21

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
Data entry locked.	System	12 Sep 2020 17:10:21
User entered 'Day 6'	System	12 Sep 2020 17:10:21

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:04:12

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-18T09:45:00', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '16fa8c02-e8d2-4f37-b8f6-c36671abdc3b' User entered 'None (0)'	System	18 Sep 2020 14:45:18
	System	18 Sep 2020 14:45:18

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:04:12

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-18T09:45:02', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '16fa8c02-e8d2-4f37-b8f6-c36671abdc3b' User entered 'None (0)'	System	18 Sep 2020 14:45:18
	System	18 Sep 2020 14:45:18

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:04:12

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-18T09:45:03', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '16fa8c02-e8d2-4f37-b8f6-c36671abdc3b' User entered 'None (0)'	System	18 Sep 2020 14:45:18
	System	18 Sep 2020 14:45:18

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:04:12

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-18T09:45:05', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '16fa8c02-e8d2-4f37-b8f6-c36671abdc3b' User entered 'None (0)'	System	18 Sep 2020 14:45:18
	System	18 Sep 2020 14:45:18

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:04:12

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-18T09:45:07', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '16fa8c02-e8d2-4f37-b8f6-c36671abdc3b' User entered 'None (0)'	System	18 Sep 2020 14:45:18
	System	18 Sep 2020 14:45:18

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:04:12

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-18T09:45:09', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '16fa8c02-e8d2-4f37-b8f6-c36671abdc3b' User entered 'None (0)'	System	18 Sep 2020 14:45:18
	System	18 Sep 2020 14:45:18

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:04:12

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 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-18T09:45:12', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '16fa8c02-e8d2-4f37-b8f6-c36671abdc3b' User entered 'No (N)'	System	18 Sep 2020 14:45:18
	System	18 Sep 2020 14:45:18

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:04:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-18T09:45:14', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '16fa8c02-e8d2-4f37-b8f6-c36671abdc3b' User entered '18 Sep 2020 09:45'	System	18 Sep 2020 14:45:18
	System	18 Sep 2020 14:45:18

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:04:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
User entered '17 Sep 2020 12:00'	System	12 Sep 2020 17:10:21

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:04:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
User entered '18 Sep 2020 11:59'	System	12 Sep 2020 17:10:21

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
Data entry locked.	System	12 Sep 2020 17:10:21
User entered 'Day 7'	System	12 Sep 2020 17:10:21

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:04:12

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-19T07:28:49', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '36ca5ece-c1b0-4f7a-aed2-5a23a9220411' User entered 'None (0)'	System	19 Sep 2020 12:29:34
	System	19 Sep 2020 12:29:34

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:04:12

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-19T07:28:52', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '36ca5ece-c1b0-4f7a-aed2-5a23a9220411' User entered 'None (0)'	System	19 Sep 2020 12:29:34
	System	19 Sep 2020 12:29:34

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:04:12

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-19T07:29:16', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '36ca5ece-c1b0-4f7a-aed2-5a23a9220411'	System	19 Sep 2020 12:29:34
User entered 'No interference with activity (1)'	System	19 Sep 2020 12:29:34

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:04:12

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-19T07:29:13', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '36ca5ece-c1b0-4f7a-aed2-5a23a9220411' User entered 'None (0)'	System	19 Sep 2020 12:29:34
	System	19 Sep 2020 12:29:34

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:04:12

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-19T07:29:10', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '36ca5ece-c1b0-4f7a-aed2-5a23a9220411' User entered 'None (0)'	System	19 Sep 2020 12:29:34
	System	19 Sep 2020 12:29:34

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:04:12

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-19T07:29:19', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '36ca5ece-c1b0-4f7a-aed2-5a23a9220411' User entered 'None (0)'	System	19 Sep 2020 12:29:34
	System	19 Sep 2020 12:29:34

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:04:12

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 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-19T07:29:23', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '36ca5ece-c1b0-4f7a-aed2-5a23a9220411' User entered 'No (N)'	System	19 Sep 2020 12:29:34
	System	19 Sep 2020 12:29:34

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:04:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-19T07:29:33', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '36ca5ece-c1b0-4f7a-aed2-5a23a9220411' User entered '19 Sep 2020 07:29'	System	19 Sep 2020 12:29:34
	System	19 Sep 2020 12:29:34

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:04:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
User entered '18 Sep 2020 12:00'	System	12 Sep 2020 17:10:21

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:04:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
User entered '19 Sep 2020 11:59'	System	12 Sep 2020 17:10:21

US3322329

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
Data entry locked.	System	19 Sep 2020 12:29:34
User entered 'Day 8'	System	19 Sep 2020 12:29:34

US3322329

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 17:04:12

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-19T12:35:25', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '9edabda2-4c9f-49ca-868a-bfcdf008ea00'	System	19 Sep 2020 17:35:37
User entered 'No interference with activity (1)'	System	19 Sep 2020 17:35:37

US3322329

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 17:04:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-19T12:35:34', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '9edabda2-4c9f-49ca-868a-bfcd008ea00'	System	19 Sep 2020 17:35:37
User entered '19 Sep 2020 12:35'	System	19 Sep 2020 17:35:37

US3322329

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 17:04:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
User entered '19 Sep 2020 12:00'	System	19 Sep 2020 12:29:34

US3322329

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 17:04:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
User entered '20 Sep 2020 11:59'	System	19 Sep 2020 12:29:34

US3322329

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
Data entry locked.	System	19 Sep 2020 12:29:34
User entered 'Day 9'	System	19 Sep 2020 12:29:34

US3322329

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 09 Jun 2021 17:04:12

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-20T12:30:40', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '0a0bb73c-89a9-4624-b8b3-e265c9e75844' User entered 'None (0)'	System	20 Sep 2020 17:30:45
	System	20 Sep 2020 17:30:45

US3322329

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 09 Jun 2021 17:04:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-20T12:30:43', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '0a0bb73c-89a9-4624-b8b3-e265c9e75844' User entered '20 Sep 2020 12:30'	System	20 Sep 2020 17:30:45
	System	20 Sep 2020 17:30:45

US3322329

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 09 Jun 2021 17:04:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
User entered '20 Sep 2020 12:00'	System	19 Sep 2020 12:29:34

US3322329

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 09 Jun 2021 17:04:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
User entered '21 Sep 2020 11:59'	System	19 Sep 2020 12:29:34

US3322329

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
Data entry locked.	System	19 Sep 2020 12:29:34
User entered 'Day 8'	System	19 Sep 2020 12:29:34

US3322329

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:04:12

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 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-19T12:35:39', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'b757d689-159b-4d13-959c-f1fff87c7411' User entered 'No (N)'	System	19 Sep 2020 17:35:47
	System	19 Sep 2020 17:35:47

US3322329

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:04:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-19T12:35:45', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'b757d689-159b-4d13-959c-f1fff87c7411' User entered '19 Sep 2020 12:35'	System	19 Sep 2020 17:35:47
	System	19 Sep 2020 17:35:47

US3322329

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:04:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
User entered '19 Sep 2020 12:00'	System	19 Sep 2020 12:29:34

US3322329

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:04:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
User entered '20 Sep 2020 11:59'	System	19 Sep 2020 12:29:34

US3322329

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
Data entry locked.	System	19 Sep 2020 12:29:34
User entered 'Day 9'	System	19 Sep 2020 12:29:34

US3322329

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 17:04:12

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 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-20T12:30:50', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '94162ac8-5060-43dc-9b43-71558aeb82b3' User entered 'No (N)'	System	20 Sep 2020 17:30:56
	System	20 Sep 2020 17:30:56

US3322329

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 17:04:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-20T12:30:53', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '94162ac8-5060-43dc-9b43-71558aeb82b3' User entered '20 Sep 2020 12:30'	System	20 Sep 2020 17:30:56
	System	20 Sep 2020 17:30:56

US3322329

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 17:04:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
User entered '20 Sep 2020 12:00'	System	19 Sep 2020 12:29:34

US3322329

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 17:04:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
User entered '21 Sep 2020 11:59'	System	19 Sep 2020 12:29:34

US3322329

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:04:12

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
DataPoint Verified.		03 Mar 2021 21:42:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'Yes (Y)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	23 Sep 2020 19:29:15

US3322329

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:04:12

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
DataPoint Verified.		03 Mar 2021 21:42:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered '22 Sep 2020'	(b) (4) Elisa Moralez (b) (4) (b) (4)	23 Sep 2020 19:29:15

US3322329

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:04:12

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
DataPoint Verified.		03 Mar 2021 21:42:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	23 Sep 2020 19:29:15

US3322329

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:04:12

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
DataPoint Verified.		03 Mar 2021 21:42:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered empty.	(b) (4) Elisa Moralez (b) (4) (b) (4)	23 Sep 2020 19:29:15

US3322329

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:04:12

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
DataPoint Verified.		03 Mar 2021 21:42:08
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'Yes (Y)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	23 Sep 2020 19:29:19

US3322329

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:04:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
User entered 'I'	System	23 Sep 2020 19:29:19

US3322329

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:04:12

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
DataPoint Verified.		03 Mar 2021 21:42:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'Yes (Y)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	29 Sep 2020 17:50:24

US3322329

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:04:12

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
DataPoint Verified.		03 Mar 2021 21:42:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered '28 Sep 2020'	(b) (4) Elisa Moralez (b) (4) (b) (4)	29 Sep 2020 17:50:24

US3322329

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:04:12

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
DataPoint Verified.		03 Mar 2021 21:42:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	29 Sep 2020 17:50:24

US3322329

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:04:12

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
DataPoint Verified.		03 Mar 2021 21:42:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered empty.	(b) (4) Elisa Moralez (b) (4) (b) (4)	29 Sep 2020 17:50:24

US3322329

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:04:12

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
DataPoint Verified.		03 Mar 2021 21:42:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'Yes (Y)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	29 Sep 2020 17:50:37

US3322329

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:04:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
User entered 'I'	System	29 Sep 2020 17:50:37

US3322329

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:04:12

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
DataPoint Verified.		03 Mar 2021 21:42:50
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'Yes (Y)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	06 Oct 2020 19:47:16

US3322329

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:04:12

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
DataPoint Verified.		03 Mar 2021 21:42:50
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered '6 Oct 2020'	(b) (4) Elisa Moralez (b) (4) (b) (4)	06 Oct 2020 19:47:16

US3322329

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:04:12

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
DataPoint Verified.		03 Mar 2021 21:42:50
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	06 Oct 2020 19:47:16

US3322329

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:04:12

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
DataPoint Verified.		03 Mar 2021 21:42:50
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered empty.	(b) (4) Elisa Moralez (b) (4) (b) (4)	06 Oct 2020 19:47:16

US3322329

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:04:12

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
DataPoint Verified.		03 Mar 2021 21:42:54
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'Yes (Y)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	06 Oct 2020 19:47:24

US3322329

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:04:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
User entered 'I'	System	06 Oct 2020 19:47:24

US3322329

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:04:12

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
DataPoint Verified.		03 Mar 2021 21:43:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:46:06

US3322329

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:04:12

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
DataPoint Verified.		03 Mar 2021 21:43:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered '15 Oct 2020'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:46:06

US3322329

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:04:12

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
DataPoint Verified.		03 Mar 2021 21:43:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:46:06

US3322329

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:04:12

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
User entered 'VISIT2'	System	15 Oct 2020 16:46:06

US3322329

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:04:12

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
User accepted default value 'Pre-Dose (PREDOSE)'		15 Oct 2020 16:46:59

US3322329

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:04:12

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
DataPoint Verified.		03 Mar 2021 21:44:00
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:46:59

US3322329

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:04:12

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
DataPoint Verified.		03 Mar 2021 21:44:00
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered '15 Oct 2020'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:46:59

US3322329

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:04:12

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
DataPoint Verified.		03 Mar 2021 21:44:00
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered '08:50'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:46:59

US3322329

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:04:12

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
User entered '15 Oct 2020 08:50'	System	15 Oct 2020 16:46:59

US3322329

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:04:12

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
DataPoint Verified.		03 Mar 2021 21:44:00
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered '96.8' F	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:46:59

US3322329

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:04:12

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
DataPoint Verified.		03 Mar 2021 21:44:00
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:46:59

US3322329

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:04:12

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
DataPoint Verified.		03 Mar 2021 21:44:00
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:46:59

US3322329

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:04:12

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
DataPoint Verified.		03 Mar 2021 21:44:00
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered '60'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:46:59

US3322329

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:04:12

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
User entered 'bpm'	System	15 Oct 2020 16:46:59

US3322329

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:04:12

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
DataPoint Verified.		03 Mar 2021 21:44:00
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered '13'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:46:59

US3322329

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:04:12

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
User entered 'breaths/min'	System	15 Oct 2020 16:46:59

US3322329

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:04:12

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
DataPoint Verified.		03 Mar 2021 21:44:00
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered '134'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:46:59

US3322329

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:04:12

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
User entered 'mmHg'	System	15 Oct 2020 16:46:59

US3322329

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:04:12

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
DataPoint Verified.		03 Mar 2021 21:44:00
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered '83'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:46:59

US3322329

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:04:12

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
User entered 'mmHg'	System	15 Oct 2020 16:46:59

US3322329

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:04:12

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
User accepted default value 'Post-Dose (POSTDOSE)'		15 Oct 2020 16:46:59

US3322329

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:04:12

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
DataPoint Verified.		03 Mar 2021 21:44:00
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:46:59

US3322329

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:04:12

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
DataPoint Verified.		03 Mar 2021 21:44:00
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered '15 Oct 2020'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:46:59

US3322329

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:04:12

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
DataPoint Verified.		03 Mar 2021 21:44:00
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered '10:26'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:46:59

US3322329

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:04:12

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
User entered '15 Oct 2020 10:26'	System	15 Oct 2020 16:46:59

US3322329

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:04:12

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
DataPoint Verified.		03 Mar 2021 21:44:00
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered '97.0' F	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:46:59

US3322329

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:04:12

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
DataPoint Verified.		03 Mar 2021 21:44:00
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:46:59

US3322329

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:04:12

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
DataPoint Verified.		03 Mar 2021 21:44:00
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:46:59

US3322329

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:04:12

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
DataPoint Verified.		03 Mar 2021 21:44:00
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered '69'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:46:59

US3322329

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:04:12

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
User entered 'bpm'	System	15 Oct 2020 16:46:59

US3322329

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:04:12

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
DataPoint Verified.		03 Mar 2021 21:44:00
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered '14'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:46:59

US3322329

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:04:12

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
User entered 'breaths/min'	System	15 Oct 2020 16:46:59

US3322329

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:04:12

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
DataPoint Verified.		03 Mar 2021 21:44:00
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered '135'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:46:59

US3322329

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:04:12

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
User entered 'mmHg'	System	15 Oct 2020 16:46:59

US3322329

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:04:12

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
DataPoint Verified.		03 Mar 2021 21:44:00
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered '85'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:46:59

US3322329

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:04:12

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
User entered 'mmHg'	System	15 Oct 2020 16:46:59

US3322329

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:04:12

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
DataPoint Verified.		03 Mar 2021 21:44:17
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:47:34

US3322329

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:04:12

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
DataPoint Verified.		03 Mar 2021 21:44:17
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered '15 Oct 2020'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:47:34

US3322329

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:04:12

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
DataPoint Verified.		03 Mar 2021 21:44:38
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'Yes (Y)'	(b) (4) Frances Saubon (b) (4) (b) (4)	15 Oct 2020 14:57:38

US3322329

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:04:12

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
DataPoint Verified.		03 Mar 2021 21:44:38
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered empty.	(b) (4) Frances Saubon (b) (4) (b) (4)	15 Oct 2020 14:57:38

US3322329

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:04:12

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)	24 Apr 2021 15:11:51
DataPoint Verified.		03 Mar 2021 21:44:38
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered empty.	(b) (4) Frances Saubon (b) (4) (b) (4)	15 Oct 2020 14:57:38

US3322329

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:04:12

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
User entered 'MRNA-1273 OR PLACEBO'	System	15 Oct 2020 14:57:38

US3322329

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:04:12

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
DataPoint Verified.		03 Mar 2021 21:44:38
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered '15 Oct 2020'	(b) (4) Frances Saubon (b) (4) (b) (4)	15 Oct 2020 14:57:38

US3322329

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:04:12

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
DataPoint Verified.		03 Mar 2021 21:44:38
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered '09:56'	(b) (4) Frances Saubon (b) (4) (b) (4)	15 Oct 2020 14:57:38

US3322329

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:04:12

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
User entered '15 Oct 2020 09:56'	System	15 Oct 2020 14:57:38

US3322329

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:04:12

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
DataPoint Verified.		03 Mar 2021 21:44:38
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'Left Arm (LEFT ARM)'	(b) (4) Frances Saubon (b) (4) (b) (4)	15 Oct 2020 14:57:38

US3322329

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:04:12

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
DataPoint Verified.		03 Mar 2021 21:44:38
User entered 'ONCE'	System	15 Oct 2020 14:57:38

US3322329

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:04:12

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
User entered 'INTRAMUSCULAR'	System	15 Oct 2020 14:57:38

US3322329

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:04:12

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
DataPoint Verified.		03 Mar 2021 21:45:01
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:48:01

US3322329

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:04:12

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
DataPoint Verified.		03 Mar 2021 21:45:01
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered '15 Oct 2020'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:48:01

US3322329

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:04:12

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
DataPoint Verified.		03 Mar 2021 21:45:01
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered '09:25'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:48:01

US3322329

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:04:12

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
User entered '15 Oct 2020 09:25'	System	15 Oct 2020 16:48:01

US3322329

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:04:12

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
DataPoint Verified.		03 Mar 2021 21:45:10
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered '15 Oct 2020'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:48:19

US3322329

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:04:12

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'		15 Oct 2020 16:48:19

US3322329

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:04:12

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
DataPoint Verified.		03 Mar 2021 21:45:10
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:48:19

US3322329

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:04:12

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
DataPoint Verified.		03 Mar 2021 21:45:10
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered '09:20'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:48:19

US3322329

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:04:12

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
User entered '15 Oct 2020 09:20'	System	15 Oct 2020 16:48:19

US3322329

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:04:12

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'		15 Oct 2020 16:48:19

US3322329

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:04:12

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
DataPoint Verified.		03 Mar 2021 21:45:10
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:48:19

US3322329

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:04:12

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
DataPoint Verified.		03 Mar 2021 21:45:10
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:48:19

US3322329

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:04:12

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
User entered empty.	System	15 Oct 2020 16:48:19

US3322329

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:04:12

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
DataPoint Verified.		03 Mar 2021 21:45:19
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:48:26

US3322329

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:04:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
User entered 'I'	System	15 Oct 2020 16:48:26

US3322329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
Data entry locked.	System	15 Oct 2020 14:57:38
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	15 Oct 2020 14:57:38

US3322329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:04:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-15T10:25:24', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '34504d6f-6378-416a-9b77-5bc333003381' User entered 'Yes (Y)'	System	15 Oct 2020 15:25:40
	System	15 Oct 2020 15:25:40

US3322329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:04:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-15T10:25:29', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '34504d6f-6378-416a-9b77-5bc333003381' User entered '97.0'	System	15 Oct 2020 15:25:40
	System	15 Oct 2020 15:25:40

US3322329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:04:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-15T10:25:33', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '34504d6f-6378-416a-9b77-5bc333003381' User entered 'No (N)'	System	15 Oct 2020 15:25:40
	System	15 Oct 2020 15:25:40

US3322329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:04:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-15T10:25:38', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '34504d6f-6378-416a-9b77-5bc333003381' User entered '15 Oct 2020 10:25'	System	15 Oct 2020 15:25:40
	System	15 Oct 2020 15:25:40

US3322329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:04:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
User entered '15 Oct 2020 10:16'	System	15 Oct 2020 14:57:38

US3322329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:04:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
User entered '15 Oct 2020 12:46'	System	15 Oct 2020 14:57:38

US3322329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
Data entry locked.	System	15 Oct 2020 14:57:38
User entered 'Day 1, after vaccination (at home)'	System	15 Oct 2020 14:57:38

US3322329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:04:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-16T02:00:25', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '67959f20-7524-42e9-822b-b901ab9c7608' User entered 'Yes (Y)'	System	16 Oct 2020 07:01:08
	System	16 Oct 2020 07:01:08

US3322329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:04:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-16T02:00:40', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '67959f20-7524-42e9-822b-b901ab9c7608' User entered '98.9'	System	16 Oct 2020 07:01:08
	System	16 Oct 2020 07:01:08

US3322329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:04:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-16T02:00:46', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '67959f20-7524-42e9-822b-b901ab9c7608'	System	16 Oct 2020 07:01:08
User entered 'Yes (Y)'	System	16 Oct 2020 07:01:08

US3322329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:04:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Patient has been followed up with, please see conmeds' (Site from System).	(b) (4)	23 Oct 2020 05:50:12
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Frances Saubon (b) (4)	22 Oct 2020 14:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-16T02:00:53', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '67959f20-7524-42e9-822b-b901ab9c7608'	(b) (4)	
User entered '1'	System	16 Oct 2020 07:01:08
	System	16 Oct 2020 07:01:08
	System	16 Oct 2020 07:01:08

US3322329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:04:12

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-16T02:00:53', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '67959f20-7524-42e9-822b-b901ab9c7608' User entered '0'	System	16 Oct 2020 07:01:08
	System	16 Oct 2020 07:01:08

US3322329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:04:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-16T02:01:02', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '67959f20-7524-42e9-822b-b901ab9c7608' User entered '16 Oct 2020 02:01'	System	16 Oct 2020 07:01:08
	System	16 Oct 2020 07:01:08

US3322329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:04:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
User entered '15 Oct 2020 13:41'	System	15 Oct 2020 14:57:38

US3322329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:04:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
User entered '16 Oct 2020 11:59'	System	15 Oct 2020 14:57:38

US3322329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
Data entry locked.	System	15 Oct 2020 14:57:38
User entered 'Day 2'	System	15 Oct 2020 14:57:38

US3322329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:04:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-16T13:27:51', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'b6342c43-5174-4630-8b66-bba4a416e0eb' User entered 'Yes (Y)'	System	16 Oct 2020 18:29:02
	System	16 Oct 2020 18:29:02

US3322329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:04:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-16T13:27:55', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'b6342c43-5174-4630-8b66-bba4a416e0eb' User entered '98.2'	System	16 Oct 2020 18:29:02
	System	16 Oct 2020 18:29:02

US3322329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:04:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-16T13:28:41', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'b6342c43-5174-4630-8b66-bba4a416e0eb' User entered 'Yes (Y)'	System	16 Oct 2020 18:29:02
	System	16 Oct 2020 18:29:02

US3322329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:04:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Patient has been followed up with, please see conmeds' (Site from System).	(b) (4), (b) (6)	23 Oct 2020 05:50:15
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-16T13:28:56', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'b6342c43-5174-4630-8b66-bba4a416e0eb' User entered '1'	Frances Saubon (b) (4) (b) (4)	22 Oct 2020 14:51:32
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	16 Oct 2020 18:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-16T13:28:56', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'b6342c43-5174-4630-8b66-bba4a416e0eb' User entered '1'	System	16 Oct 2020 18:29:02
User entered '1'	System	16 Oct 2020 18:29:02

US3322329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:04:12

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-16T13:28:56', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'b6342c43-5174-4630-8b66-bba4a416e0eb' User entered '0'	System	16 Oct 2020 18:29:02
	System	16 Oct 2020 18:29:02

US3322329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:04:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-16T13:28:59', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'b6342c43-5174-4630-8b66-bba4a416e0eb' User entered '16 Oct 2020 13:28'	System	16 Oct 2020 18:29:02
	System	16 Oct 2020 18:29:02

US3322329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:04:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
User entered '16 Oct 2020 12:00'	System	15 Oct 2020 14:57:38

US3322329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:04:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
User entered '17 Oct 2020 11:59'	System	15 Oct 2020 14:57:38

US3322329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
Data entry locked.	System	15 Oct 2020 14:57:38
User entered 'Day 3'	System	15 Oct 2020 14:57:38

US3322329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:04:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-17T12:03:16', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '3d394075-d55a-4060-928d-6e819de39248' User entered 'Yes (Y)'	System	17 Oct 2020 17:03:38
	System	17 Oct 2020 17:03:38

US3322329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:04:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-17T12:03:20', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '3d394075-d55a-4060-928d-6e819de39248' User entered '97.3'	System	17 Oct 2020 17:03:38
	System	17 Oct 2020 17:03:38

US3322329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:04:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-17T12:03:25', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '3d394075-d55a-4060-928d-6e819de39248'	System	17 Oct 2020 17:03:38
User entered 'Yes (Y)'	System	17 Oct 2020 17:03:38

US3322329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:04:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).		23 Oct 2020 05:50:18
Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Patient has been followed up with, please see conmeds' (Site from System).	Frances Saubon (b) (4) (b) (4)	22 Oct 2020 14:51:36
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	17 Oct 2020 17:03:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-17T12:03:30', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '3d394075-d55a-4060-928d-6e819de39248'	System	17 Oct 2020 17:03:38
User entered '1'	System	17 Oct 2020 17:03:38

US3322329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:04:12

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-17T12:03:30', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '3d394075-d55a-4060-928d-6e819de39248' User entered '0'	System	17 Oct 2020 17:03:38
	System	17 Oct 2020 17:03:38

US3322329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:04:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-17T12:03:34', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '3d394075-d55a-4060-928d-6e819de39248' User entered '17 Oct 2020 12:03'	System	17 Oct 2020 17:03:38
	System	17 Oct 2020 17:03:38

US3322329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:04:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
User entered '17 Oct 2020 12:00'	System	15 Oct 2020 14:57:38

US3322329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:04:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
User entered '18 Oct 2020 11:59'	System	15 Oct 2020 14:57:38

US3322329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
Data entry locked.	System	15 Oct 2020 14:57:38
User entered 'Day 4'	System	15 Oct 2020 14:57:38

US3322329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:04:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-18T16:19:31', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '9157e7f2-d39c-4467-82f3-afe67c3b050f' User entered 'Yes (Y)'	System	18 Oct 2020 21:19:46
	System	18 Oct 2020 21:19:46

US3322329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:04:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-18T16:19:35', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '9157e7f2-d39c-4467-82f3-afe67c3b050f' User entered '96.8'	System	18 Oct 2020 21:19:46
	System	18 Oct 2020 21:19:46

US3322329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:04:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-18T16:19:38', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '9157e7f2-d39c-4467-82f3-afe67c3b050f' User entered 'No (N)'	System	18 Oct 2020 21:19:46
	System	18 Oct 2020 21:19:46

US3322329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:04:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-18T16:19:42', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '9157e7f2-d39c-4467-82f3-afe67c3b050f' User entered '18 Oct 2020 16:19'	System	18 Oct 2020 21:19:46
	System	18 Oct 2020 21:19:46

US3322329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:04:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
User entered '18 Oct 2020 12:00'	System	15 Oct 2020 14:57:38

US3322329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:04:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
User entered '19 Oct 2020 11:59'	System	15 Oct 2020 14:57:38

US3322329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
Data entry locked.	System	15 Oct 2020 14:57:38
User entered 'Day 5'	System	15 Oct 2020 14:57:38

US3322329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:04:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-19T22:52:30', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'c0bd7a6f-b7e6-4a99-8d57-e16ae237be3d' User entered 'Yes (Y)'	System	20 Oct 2020 03:52:52
	System	20 Oct 2020 03:52:52

US3322329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:04:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-19T22:52:42', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'c0bd7a6f-b7e6-4a99-8d57-e16ae237be3d' User entered '97.0'	System	20 Oct 2020 03:52:52
	System	20 Oct 2020 03:52:52

US3322329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:04:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-19T22:52:46', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'c0bd7a6f-b7e6-4a99-8d57-e16ae237be3d' User entered 'No (N)'	System	20 Oct 2020 03:52:52
	System	20 Oct 2020 03:52:52

US3322329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:04:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-19T22:52:50', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'c0bd7a6f-b7e6-4a99-8d57-e16ae237be3d' User entered '19 Oct 2020 22:52'	System	20 Oct 2020 03:52:52
	System	20 Oct 2020 03:52:52

US3322329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:04:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
User entered '19 Oct 2020 12:00'	System	15 Oct 2020 14:57:38

US3322329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:04:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
User entered '20 Oct 2020 11:59'	System	15 Oct 2020 14:57:38

US3322329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
Data entry locked.	System	15 Oct 2020 14:57:38
User entered 'Day 6'	System	15 Oct 2020 14:57:38

US3322329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:04:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-20T23:32:44', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'aeaa420e-2725-45a1-8c90-5344db6e159b' User entered 'Yes (Y)'	System	21 Oct 2020 04:32:57
	System	21 Oct 2020 04:32:57

US3322329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:04:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-20T23:32:49', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'aeaa420e-2725-45a1-8c90-5344db6e159b' User entered '97.8'	System	21 Oct 2020 04:32:57
	System	21 Oct 2020 04:32:57

US3322329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:04:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-20T23:32:52', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'aeaa420e-2725-45a1-8c90-5344db6e159b' User entered 'No (N)'	System	21 Oct 2020 04:32:57
	System	21 Oct 2020 04:32:57

US3322329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:04:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-20T23:32:55', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'aeaa420e-2725-45a1-8c90-5344db6e159b' User entered '20 Oct 2020 23:32'	System	21 Oct 2020 04:32:57
	System	21 Oct 2020 04:32:57

US3322329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:04:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
User entered '20 Oct 2020 12:00'	System	15 Oct 2020 14:57:38

US3322329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:04:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
User entered '21 Oct 2020 11:59'	System	15 Oct 2020 14:57:38

US3322329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
Data entry locked.	System	15 Oct 2020 14:57:38
User entered 'Day 7'	System	15 Oct 2020 14:57:38

US3322329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:04:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-21T22:20:36', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'bb14cfd7-042a-4b70-9f2d-43cf6fd6a15a' User entered 'Yes (Y)'	System	22 Oct 2020 03:20:53
	System	22 Oct 2020 03:20:53

US3322329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:04:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-21T22:20:40', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'bb14cfd7-042a-4b70-9f2d-43cf6fd6a15a' User entered '97.8'	System	22 Oct 2020 03:20:53
	System	22 Oct 2020 03:20:53

US3322329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:04:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-21T22:20:48', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'bb14cfd7-042a-4b70-9f2d-43cf6fd6a15a' User entered 'No (N)'	System	22 Oct 2020 03:20:53
	System	22 Oct 2020 03:20:53

US3322329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:04:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-21T22:20:52', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'bb14cfd7-042a-4b70-9f2d-43cf6fd6a15a' User entered '21 Oct 2020 22:20'	System	22 Oct 2020 03:20:53
	System	22 Oct 2020 03:20:53

US3322329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:04:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
User entered '21 Oct 2020 12:00'	System	15 Oct 2020 14:57:38

US3322329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:04:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
User entered '22 Oct 2020 11:59'	System	15 Oct 2020 14:57:38

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
Data entry locked.	System	15 Oct 2020 14:57:38
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	15 Oct 2020 14:57:38

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:04:12

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 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-15T10:25:44', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '271b1895-7bf4-4d79-a44c-d913be6065f0' User entered 'None (1)'	System	15 Oct 2020 15:26:04
	System	15 Oct 2020 15:26:04

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:04:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-15T10:25:49', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '271b1895-7bf4-4d79-a44c-d913be6065f0' User entered 'No (N)'	System	15 Oct 2020 15:26:04
	System	15 Oct 2020 15:26:04

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:04:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-15T10:25:52', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '271b1895-7bf4-4d79-a44c-d913be6065f0' User entered 'No (N)'	System	15 Oct 2020 15:26:04
	System	15 Oct 2020 15:26:04

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:04:12

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 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-15T10:25:56', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '271b1895-7bf4-4d79-a44c-d913be6065f0' User entered 'None (1)'	System	15 Oct 2020 15:26:04
	System	15 Oct 2020 15:26:04

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:04:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-15T10:26:00', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '271b1895-7bf4-4d79-a44c-d913be6065f0' User entered '15 Oct 2020 10:26'	System	15 Oct 2020 15:26:04
	System	15 Oct 2020 15:26:04

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:04:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
User entered '15 Oct 2020 10:16'	System	15 Oct 2020 14:57:38

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:04:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
User entered '15 Oct 2020 12:46'	System	15 Oct 2020 14:57:38

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
Data entry locked.	System	15 Oct 2020 14:57:38
User entered 'Day 1, after vaccination (at home)'	System	15 Oct 2020 14:57:38

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:04:12

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 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-16T02:01:18', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '0a3ccf2c-5aa4-4701-91c9-8e7c3506945b'	System	16 Oct 2020 07:02:37
User entered 'Does not interfere with activity (2)'	System	16 Oct 2020 07:02:37

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:04:12

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-16T02:01:50', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '0a3ccf2c-5aa4-4701-91c9-8e7c3506945b' User entered 'No (N)'	System	16 Oct 2020 07:02:37
	System	16 Oct 2020 07:02:37

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:04:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-16T02:01:54', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '0a3ccf2c-5aa4-4701-91c9-8e7c3506945b' User entered 'Yes (Y)'	System	16 Oct 2020 07:02:37
	System	16 Oct 2020 07:02:37

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:04:12

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-16T02:02:12', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '0a3ccf2c-5aa4-4701-91c9-8e7c3506945b' User entered '20'	System	16 Oct 2020 07:02:37
	System	16 Oct 2020 07:02:37

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:04:12

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 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-16T02:02:26', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '0a3ccf2c-5aa4-4701-91c9-8e7c3506945b' User entered 'None (1)'	System	16 Oct 2020 07:02:37
	System	16 Oct 2020 07:02:37

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:04:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-16T02:02:32', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '0a3ccf2c-5aa4-4701-91c9-8e7c3506945b' User entered '16 Oct 2020 02:02'	System	16 Oct 2020 07:02:37
	System	16 Oct 2020 07:02:37

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:04:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
User entered '15 Oct 2020 13:41'	System	15 Oct 2020 14:57:38

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:04:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
User entered '16 Oct 2020 11:59'	System	15 Oct 2020 14:57:38

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
Data entry locked.	System	15 Oct 2020 14:57:38
User entered 'Day 2'	System	15 Oct 2020 14:57:38

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:04:12

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 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-16T13:20:58', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'd19f29dc-9230-4d8e-afcd-a0459defc4a3'	System	16 Oct 2020 18:22:22
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	16 Oct 2020 18:22:22

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:04:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-16T13:21:17', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'd19f29dc-9230-4d8e-afcd-a0459defc4a3' User entered 'No (N)'	System	16 Oct 2020 18:22:22
	System	16 Oct 2020 18:22:22

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:04:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-16T13:21:20', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'd19f29dc-9230-4d8e-afcd-a0459defc4a3' User entered 'Yes (Y)'	System	16 Oct 2020 18:22:22
	System	16 Oct 2020 18:22:22

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:04:12

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-16T13:21:46', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'd19f29dc-9230-4d8e-afcd-a0459defc4a3' User entered '76'	System	16 Oct 2020 18:22:22
	System	16 Oct 2020 18:22:22

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:04:12

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 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-16T13:22:04', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'd19f29dc-9230-4d8e-afcd-a0459defc4a3' User entered 'Does not interfere with activity (2)'	System	16 Oct 2020 18:22:22
	System	16 Oct 2020 18:22:22

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:04:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-16T13:22:17', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'd19f29dc-9230-4d8e-afcd-a0459defc4a3' User entered '16 Oct 2020 13:22'	System	16 Oct 2020 18:22:22
	System	16 Oct 2020 18:22:22

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:04:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
User entered '16 Oct 2020 12:00'	System	15 Oct 2020 14:57:38

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:04:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
User entered '17 Oct 2020 11:59'	System	15 Oct 2020 14:57:38

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
Data entry locked.	System	15 Oct 2020 14:57:38
User entered 'Day 3'	System	15 Oct 2020 14:57:38

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:04:12

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 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-17T12:00:38', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'e693a930-0d43-47f3-b86b-2babfb9dacfc'	System	17 Oct 2020 17:01:49
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	17 Oct 2020 17:01:49

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:04:12

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-17T12:00:41', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'e693a930-0d43-47f3-b86b-2babfb9dacfc' User entered 'Yes (Y)'	System	17 Oct 2020 17:01:49
	System	17 Oct 2020 17:01:49

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:04:12

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-17T12:01:02', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'e693a930-0d43-47f3-b86b-2babfb9dacfc' User entered '100'	System	17 Oct 2020 17:01:49
	System	17 Oct 2020 17:01:49

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:04:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-17T12:01:05', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'e693a930-0d43-47f3-b86b-2babfb9dacfc' User entered 'Yes (Y)'	System	17 Oct 2020 17:01:49
	System	17 Oct 2020 17:01:49

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:04:12

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-17T12:01:28', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'e693a930-0d43-47f3-b86b-2babfb9dacfc'	System	17 Oct 2020 17:01:49
User entered '125'	System	17 Oct 2020 17:01:49

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:04:12

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 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-17T12:01:38', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'e693a930-0d43-47f3-b86b-2babfb9dacfc'	System	17 Oct 2020 17:01:49
User entered 'Does not interfere with activity (2)'	System	17 Oct 2020 17:01:49

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:04:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-17T12:01:47', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'e693a930-0d43-47f3-b86b-2babfb9dacfc' User entered '17 Oct 2020 12:01'	System	17 Oct 2020 17:01:49
	System	17 Oct 2020 17:01:49

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:04:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
User entered '17 Oct 2020 12:00'	System	15 Oct 2020 14:57:38

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:04:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
User entered '18 Oct 2020 11:59'	System	15 Oct 2020 14:57:38

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
Data entry locked.	System	15 Oct 2020 14:57:38
User entered 'Day 4'	System	15 Oct 2020 14:57:38

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:04:12

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 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-18T16:19:49', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '02b663bc-03e6-4af2-8d62-2f5f78797c7d' User entered 'Does not interfere with activity (2)'	System	18 Oct 2020 21:20:52
	System	18 Oct 2020 21:20:52

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:04:12

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-18T16:19:52', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '02b663bc-03e6-4af2-8d62-2f5f78797c7d' User entered 'Yes (Y)'	System	18 Oct 2020 21:20:52
	System	18 Oct 2020 21:20:52

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:04:12

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-18T16:20:15', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '02b663bc-03e6-4af2-8d62-2f5f78797c7d' User entered '64'	System	18 Oct 2020 21:20:52
	System	18 Oct 2020 21:20:52

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:04:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-18T16:20:19', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '02b663bc-03e6-4af2-8d62-2f5f78797c7d' User entered 'Yes (Y)'	System	18 Oct 2020 21:20:52
	System	18 Oct 2020 21:20:52

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:04:12

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-18T16:20:31', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '02b663bc-03e6-4af2-8d62-2f5f78797c7d' User entered '55'	System	18 Oct 2020 21:20:52
	System	18 Oct 2020 21:20:52

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:04:12

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 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-18T16:20:44', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '02b663bc-03e6-4af2-8d62-2f5f78797c7d'	System	18 Oct 2020 21:20:52
User entered 'Does not interfere with activity (2)'	System	18 Oct 2020 21:20:52

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:04:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-18T16:20:47', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '02b663bc-03e6-4af2-8d62-2f5f78797c7d' User entered '18 Oct 2020 16:20'	System	18 Oct 2020 21:20:52
	System	18 Oct 2020 21:20:52

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:04:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
User entered '18 Oct 2020 12:00'	System	15 Oct 2020 14:57:38

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:04:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
User entered '19 Oct 2020 11:59'	System	15 Oct 2020 14:57:38

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
Data entry locked.	System	15 Oct 2020 14:57:38
User entered 'Day 5'	System	15 Oct 2020 14:57:38

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:04:12

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 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-19T22:52:57', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '02aa32cc-0ccb-4245-bc49-b7188f917b3b'	System	20 Oct 2020 03:54:19
User entered 'Does not interfere with activity (2)'	System	20 Oct 2020 03:54:19

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:04:12

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-19T22:53:57', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '02aa32cc-0ccb-4245-bc49-b7188f917b3b' User entered 'Yes (Y)'	System	20 Oct 2020 03:54:19
	System	20 Oct 2020 03:54:19

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:04:12

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-19T22:54:02', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '02aa32cc-0ccb-4245-bc49-b7188f917b3b' User entered '50'	System	20 Oct 2020 03:54:19
	System	20 Oct 2020 03:54:19

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:04:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-19T22:54:05', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '02aa32cc-0ccb-4245-bc49-b7188f917b3b' User entered 'Yes (Y)'	System	20 Oct 2020 03:54:19
	System	20 Oct 2020 03:54:19

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:04:12

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-19T22:54:08', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '02aa32cc-0ccb-4245-bc49-b7188f917b3b' User entered '50'	System	20 Oct 2020 03:54:19
	System	20 Oct 2020 03:54:19

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:04:12

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 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-19T22:54:12', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '02aa32cc-0ccb-4245-bc49-b7188f917b3b' User entered 'None (1)'	System	20 Oct 2020 03:54:19
	System	20 Oct 2020 03:54:19

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:04:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-19T22:54:16', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '02aa32cc-0ccb-4245-bc49-b7188f917b3b' User entered '19 Oct 2020 22:54'	System	20 Oct 2020 03:54:19
	System	20 Oct 2020 03:54:19

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:04:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
User entered '19 Oct 2020 12:00'	System	15 Oct 2020 14:57:38

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:04:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
User entered '20 Oct 2020 11:59'	System	15 Oct 2020 14:57:38

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
Data entry locked.	System	15 Oct 2020 14:57:38
User entered 'Day 6'	System	15 Oct 2020 14:57:38

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:04:12

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 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-20T23:33:09', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '05c169c8-58fb-41cb-a6bd-2ce4185b3c61' User entered 'Does not interfere with activity (2)'	System	21 Oct 2020 04:33:53
	System	21 Oct 2020 04:33:53

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:04:12

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-20T23:33:26', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '05c169c8-58fb-41cb-a6bd-2ce4185b3c61' User entered 'Yes (Y)'	System	21 Oct 2020 04:33:53
	System	21 Oct 2020 04:33:53

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:04:12

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-20T23:33:30', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '05c169c8-58fb-41cb-a6bd-2ce4185b3c61' User entered '40'	System	21 Oct 2020 04:33:53
	System	21 Oct 2020 04:33:53

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:04:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-20T23:33:36', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '05c169c8-58fb-41cb-a6bd-2ce4185b3c61' User entered 'Yes (Y)'	System	21 Oct 2020 04:33:53
	System	21 Oct 2020 04:33:53

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:04:12

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-20T23:33:43', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '05c169c8-58fb-41cb-a6bd-2ce4185b3c61' User entered '25'	System	21 Oct 2020 04:33:53
	System	21 Oct 2020 04:33:53

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:04:12

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 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-20T23:33:46', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '05c169c8-58fb-41cb-a6bd-2ce4185b3c61' User entered 'None (1)'	System	21 Oct 2020 04:33:53
	System	21 Oct 2020 04:33:53

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:04:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-20T23:33:50', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '05c169c8-58fb-41cb-a6bd-2ce4185b3c61' User entered '20 Oct 2020 23:33'	System	21 Oct 2020 04:33:53
	System	21 Oct 2020 04:33:53

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:04:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
User entered '20 Oct 2020 12:00'	System	15 Oct 2020 14:57:38

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:04:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
User entered '21 Oct 2020 11:59'	System	15 Oct 2020 14:57:38

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
Data entry locked.	System	15 Oct 2020 14:57:38
User entered 'Day 7'	System	15 Oct 2020 14:57:38

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:04:12

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 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-21T22:21:12', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'fc35cc5f-fe99-4e8c-a7e0-57a6b96369db' User entered 'None (1)'	System	22 Oct 2020 03:21:51
	System	22 Oct 2020 03:21:51

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:04:12

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-21T22:21:16', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'fc35cc5f-fe99-4e8c-a7e0-57a6b96369db' User entered 'Yes (Y)'	System	22 Oct 2020 03:21:51
	System	22 Oct 2020 03:21:51

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:04:12

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-21T22:21:29', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'fc35cc5f-fe99-4e8c-a7e0-57a6b96369db' User entered '35'	System	22 Oct 2020 03:21:51
	System	22 Oct 2020 03:21:51

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:04:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-21T22:21:33', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'fc35cc5f-fe99-4e8c-a7e0-57a6b96369db' User entered 'Yes (Y)'	System	22 Oct 2020 03:21:51
	System	22 Oct 2020 03:21:51

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:04:12

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-21T22:21:37', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'fc35cc5f-fe99-4e8c-a7e0-57a6b96369db' User entered '20'	System	22 Oct 2020 03:21:51
	System	22 Oct 2020 03:21:51

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:04:12

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 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-21T22:21:45', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'fc35cc5f-fe99-4e8c-a7e0-57a6b96369db' User entered 'None (1)'	System	22 Oct 2020 03:21:51
	System	22 Oct 2020 03:21:51

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:04:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-21T22:21:49', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'fc35cc5f-fe99-4e8c-a7e0-57a6b96369db' User entered '21 Oct 2020 22:21'	System	22 Oct 2020 03:21:51
	System	22 Oct 2020 03:21:51

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:04:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
User entered '21 Oct 2020 12:00'	System	15 Oct 2020 14:57:38

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:04:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
User entered '22 Oct 2020 11:59'	System	15 Oct 2020 14:57:38

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 22:04:00
Data entry locked.	System	15 Oct 2020 14:57:38
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	15 Oct 2020 14:57:38

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:04:12

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 22:04:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-15T10:26:10', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '1fe659f3-4485-4b01-9c90-4cb10333c782'	System	15 Oct 2020 15:26:32
User entered 'None (0)'	System	15 Oct 2020 15:26:32

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:04:12

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 22:04:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-15T10:26:12', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '1fe659f3-4485-4b01-9c90-4cb10333c782' User entered 'None (0)'	System	15 Oct 2020 15:26:32
	System	15 Oct 2020 15:26:32

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:04:12

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 22:04:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-15T10:26:14', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '1fe659f3-4485-4b01-9c90-4cb10333c782' User entered 'None (0)'	System	15 Oct 2020 15:26:32
	System	15 Oct 2020 15:26:32

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:04:12

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 22:04:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-15T10:26:17', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '1fe659f3-4485-4b01-9c90-4cb10333c782' User entered 'None (0)'	System	15 Oct 2020 15:26:32
	System	15 Oct 2020 15:26:32

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:04:12

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 22:04:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-15T10:26:19', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '1fe659f3-4485-4b01-9c90-4cb10333c782' User entered 'None (0)'	System	15 Oct 2020 15:26:32
	System	15 Oct 2020 15:26:32

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:04:12

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 22:04:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-15T10:26:21', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '1fe659f3-4485-4b01-9c90-4cb10333c782' User entered 'None (0)'	System	15 Oct 2020 15:26:32
	System	15 Oct 2020 15:26:32

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:04:12

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)	08 Mar 2021 22:04:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-15T10:26:25', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '1fe659f3-4485-4b01-9c90-4cb10333c782' User entered 'No (N)'	System	15 Oct 2020 15:26:32
	System	15 Oct 2020 15:26:32

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:04:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 22:04:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-15T10:26:28', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '1fe659f3-4485-4b01-9c90-4cb10333c782'	System	15 Oct 2020 15:26:32
User entered '15 Oct 2020 10:26'	System	15 Oct 2020 15:26:32

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:04:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 22:04:00
User entered '15 Oct 2020 10:16'	System	15 Oct 2020 14:57:38

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:04:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 22:04:00
User entered '15 Oct 2020 12:46'	System	15 Oct 2020 14:57:38

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 22:04:00
Data entry locked.	System	15 Oct 2020 14:57:38
User entered 'Day 1, after vaccination (at home)'	System	15 Oct 2020 14:57:38

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:04:12

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 22:04:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-16T02:02:47', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'f49c8327-28c2-4091-8b03-3e1bd83c5f20'	System	16 Oct 2020 07:03:34
User entered 'No interference with activity (1)'	System	16 Oct 2020 07:03:34

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:04:12

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 22:04:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-16T02:02:54', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'f49c8327-28c2-4091-8b03-3e1bd83c5f20' User entered 'None (0)'	System	16 Oct 2020 07:03:34
	System	16 Oct 2020 07:03:34

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:04:12

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 22:04:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-16T02:03:05', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'f49c8327-28c2-4091-8b03-3e1bd83c5f20' User entered 'None (0)'	System	16 Oct 2020 07:03:34
	System	16 Oct 2020 07:03:34

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:04:12

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 22:04:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-16T02:03:09', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'f49c8327-28c2-4091-8b03-3e1bd83c5f20' User entered 'None (0)'	System	16 Oct 2020 07:03:34
	System	16 Oct 2020 07:03:34

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:04:12

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 22:04:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-16T02:03:12', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'f49c8327-28c2-4091-8b03-3e1bd83c5f20' User entered 'None (0)'	System	16 Oct 2020 07:03:34
	System	16 Oct 2020 07:03:34

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:04:12

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 22:04:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-16T02:03:22', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'f49c8327-28c2-4091-8b03-3e1bd83c5f20' User entered 'None (0)'	System	16 Oct 2020 07:03:34
	System	16 Oct 2020 07:03:34

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:04:12

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)	08 Mar 2021 22:04:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-16T02:03:27', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'f49c8327-28c2-4091-8b03-3e1bd83c5f20' User entered 'No (N)'	System	16 Oct 2020 07:03:34
	System	16 Oct 2020 07:03:34

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:04:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 22:04:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-16T02:03:32', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'f49c8327-28c2-4091-8b03-3e1bd83c5f20' User entered '16 Oct 2020 02:03'	System	16 Oct 2020 07:03:34
	System	16 Oct 2020 07:03:34

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:04:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 22:04:00
User entered '15 Oct 2020 13:41'	System	15 Oct 2020 14:57:38

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:04:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 22:04:00
User entered '16 Oct 2020 11:59'	System	15 Oct 2020 14:57:38

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 22:04:00
Data entry locked.	System	15 Oct 2020 14:57:38
User entered 'Day 2'	System	15 Oct 2020 14:57:38

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:04:12

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 22:04:00
User closed query 'Per CDM: Please confirm if conmed #1 date is correct, since diary dose day 2 was 16 Oct 20 and start date for conmed given for muscle pain (log line #1) is 16 Sep 2020.' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 17:44:24
Query 'Per CDM: Please confirm if conmed #1 date is correct, since diary dose day 2 was 16 Oct 20 and start date for conmed given for muscle pain (log line #1) is 16 Sep 2020.' answered with 'yes' (Site from DM).	Elisa Moralez (b) (4) (b) (4)	03 Mar 2021 20:11:37
User opened query 'Per CDM: Please confirm if conmed #1 date is correct, since diary dose day 2 was 16 Oct 20 and start date for conmed given for muscle pain (log line #1) is 16 Sep 2020.' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 17:22:12
User closed query 'Per DM CLR: Per Diary Dose 2 Day 2 and 3, Pain at Injection Site and Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise, please clarify.' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 17:22:12
Query 'Per DM CLR: Per Diary Dose 2 Day 2 and 3, Pain at Injection Site and Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise, please clarify.' answered with 'patient confirmed error and that medication was only taken for muscle pain, which is entered in conmeds' (Site from DM).	Elisa Moralez (b) (4) (b) (4)	25 Feb 2021 19:39:36

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:04:12

HEADACHE

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Per Diary Dose 2 Day 2 and 3, Pain at Injection Site and Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise, please clarify.' (Site from DM). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-16T13:22:33', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '0e691a2c-d6eb-4d49-a48a-3528c1a83e74'	(b) (4), (b) (6)	23 Feb 2021 01:59:45
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	16 Oct 2020 18:23:14

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:04:12

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 22:04:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-16T13:22:45', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '0e691a2c-d6eb-4d49-a48a-3528c1a83e74'	System	16 Oct 2020 18:23:14
User entered 'Some interference with activity (2)'	System	16 Oct 2020 18:23:14

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:04:12

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 22:04:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-16T13:22:51', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '0e691a2c-d6eb-4d49-a48a-3528c1a83e74' User entered 'None (0)'	System	16 Oct 2020 18:23:14
	System	16 Oct 2020 18:23:14

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:04:12

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 22:04:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-16T13:22:54', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '0e691a2c-d6eb-4d49-a48a-3528c1a83e74' User entered 'None (0)'	System	16 Oct 2020 18:23:14
	System	16 Oct 2020 18:23:14

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:04:12

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 22:04:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-16T13:22:57', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '0e691a2c-d6eb-4d49-a48a-3528c1a83e74' User entered 'None (0)'	System	16 Oct 2020 18:23:14
	System	16 Oct 2020 18:23:14

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:04:12

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 22:04:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-16T13:23:00', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '0e691a2c-d6eb-4d49-a48a-3528c1a83e74' User entered 'None (0)'	System	16 Oct 2020 18:23:14
	System	16 Oct 2020 18:23:14

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:04:12

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)	08 Mar 2021 22:04:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-16T13:23:07', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '0e691a2c-d6eb-4d49-a48a-3528c1a83e74' User entered 'No (N)'	System	16 Oct 2020 18:23:14
	System	16 Oct 2020 18:23:14

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:04:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 22:04:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-16T13:23:12', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '0e691a2c-d6eb-4d49-a48a-3528c1a83e74' User entered '16 Oct 2020 13:23'	System	16 Oct 2020 18:23:14
	System	16 Oct 2020 18:23:14

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:04:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 22:04:00
User entered '16 Oct 2020 12:00'	System	15 Oct 2020 14:57:38

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:04:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 22:04:00
User entered '17 Oct 2020 11:59'	System	15 Oct 2020 14:57:38

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 22:04:00
Data entry locked.	System	15 Oct 2020 14:57:38
User entered 'Day 3'	System	15 Oct 2020 14:57:38

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:04:12

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 22:04:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-17T12:01:55', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '00305dac-b44c-4038-9e05-9f96be3c2961'	System	17 Oct 2020 17:02:30
User entered 'No interference with activity (1)'	System	17 Oct 2020 17:02:30

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:04:12

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 22:04:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-17T12:02:01', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '00305dac-b44c-4038-9e05-9f96be3c2961'	System	17 Oct 2020 17:02:30
User entered 'No interference with activity (1)'	System	17 Oct 2020 17:02:30

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:04:12

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 22:04:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-17T12:02:06', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '00305dac-b44c-4038-9e05-9f96be3c2961' User entered 'None (0)'	System	17 Oct 2020 17:02:30
	System	17 Oct 2020 17:02:30

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:04:12

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 22:04:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-17T12:02:09', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '00305dac-b44c-4038-9e05-9f96be3c2961' User entered 'None (0)'	System	17 Oct 2020 17:02:30
	System	17 Oct 2020 17:02:30

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:04:12

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 22:04:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-17T12:02:11', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '00305dac-b44c-4038-9e05-9f96be3c2961' User entered 'None (0)'	System	17 Oct 2020 17:02:30
	System	17 Oct 2020 17:02:30

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:04:12

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 22:04:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-17T12:02:14', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '00305dac-b44c-4038-9e05-9f96be3c2961' User entered 'None (0)'	System	17 Oct 2020 17:02:30
	System	17 Oct 2020 17:02:30

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:04:12

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)	08 Mar 2021 22:04:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-17T12:02:24', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '00305dac-b44c-4038-9e05-9f96be3c2961' User entered 'Yes (Y)'	System	17 Oct 2020 17:02:30
	System	17 Oct 2020 17:02:30

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:04:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 22:04:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-17T12:02:28', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '00305dac-b44c-4038-9e05-9f96be3c2961' User entered '17 Oct 2020 12:02'	System	17 Oct 2020 17:02:30
	System	17 Oct 2020 17:02:30

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:04:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 22:04:00
User entered '17 Oct 2020 12:00'	System	15 Oct 2020 14:57:38

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:04:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 22:04:00
User entered '18 Oct 2020 11:59'	System	15 Oct 2020 14:57:38

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 22:04:00
Data entry locked.	System	15 Oct 2020 14:57:38
User entered 'Day 4'	System	15 Oct 2020 14:57:38

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:04:12

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 22:04:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-18T16:20:53', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'b68eb26b-127d-43ee-9ca3-9bb735268daa'	System	18 Oct 2020 21:21:19
User entered 'No interference with activity (1)'	System	18 Oct 2020 21:21:19

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:04:12

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 22:04:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-18T16:20:55', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'b68eb26b-127d-43ee-9ca3-9bb735268daa' User entered 'None (0)'	System	18 Oct 2020 21:21:19
	System	18 Oct 2020 21:21:19

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:04:12

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 22:04:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-18T16:20:57', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'b68eb26b-127d-43ee-9ca3-9bb735268daa' User entered 'None (0)'	System	18 Oct 2020 21:21:19
	System	18 Oct 2020 21:21:19

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:04:12

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 22:04:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-18T16:20:59', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'b68eb26b-127d-43ee-9ca3-9bb735268daa' User entered 'None (0)'	System	18 Oct 2020 21:21:19
	System	18 Oct 2020 21:21:19

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:04:12

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 22:04:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-18T16:21:01', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'b68eb26b-127d-43ee-9ca3-9bb735268daa' User entered 'None (0)'	System	18 Oct 2020 21:21:19
	System	18 Oct 2020 21:21:19

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:04:12

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 22:04:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-18T16:21:03', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'b68eb26b-127d-43ee-9ca3-9bb735268daa' User entered 'None (0)'	System	18 Oct 2020 21:21:19
	System	18 Oct 2020 21:21:19

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:04:12

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)	08 Mar 2021 22:04:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-18T16:21:10', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'b68eb26b-127d-43ee-9ca3-9bb735268daa' User entered 'No (N)'	System	18 Oct 2020 21:21:19
	System	18 Oct 2020 21:21:19

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:04:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 22:04:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-18T16:21:14', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'b68eb26b-127d-43ee-9ca3-9bb735268daa' User entered '18 Oct 2020 16:21'	System	18 Oct 2020 21:21:19
	System	18 Oct 2020 21:21:19

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:04:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 22:04:00
User entered '18 Oct 2020 12:00'	System	15 Oct 2020 14:57:38

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:04:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 22:04:00
User entered '19 Oct 2020 11:59'	System	15 Oct 2020 14:57:38

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 22:04:00
Data entry locked.	System	15 Oct 2020 14:57:38
User entered 'Day 5'	System	15 Oct 2020 14:57:38

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:04:12

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 22:04:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-19T22:54:21', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '7fd13623-f08d-4204-b32b-3ed10339f85a' User entered 'None (0)'	System	20 Oct 2020 03:55:05
	System	20 Oct 2020 03:55:05

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:04:12

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 22:04:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-19T22:54:23', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '7fd13623-f08d-4204-b32b-3ed10339f85a' User entered 'None (0)'	System	20 Oct 2020 03:55:05
	System	20 Oct 2020 03:55:05

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:04:12

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 22:04:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-19T22:54:25', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '7fd13623-f08d-4204-b32b-3ed10339f85a' User entered 'None (0)'	System	20 Oct 2020 03:55:05
	System	20 Oct 2020 03:55:05

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:04:12

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 22:04:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-19T22:54:27', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '7fd13623-f08d-4204-b32b-3ed10339f85a' User entered 'None (0)'	System	20 Oct 2020 03:55:05
	System	20 Oct 2020 03:55:05

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:04:12

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 22:04:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-19T22:54:30', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '7fd13623-f08d-4204-b32b-3ed10339f85a' User entered 'None (0)'	System	20 Oct 2020 03:55:05
	System	20 Oct 2020 03:55:05

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:04:12

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 22:04:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-19T22:54:36', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '7fd13623-f08d-4204-b32b-3ed10339f85a' User entered 'None (0)'	System	20 Oct 2020 03:55:05
	System	20 Oct 2020 03:55:05

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:04:12

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)	08 Mar 2021 22:04:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-19T22:54:52', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '7fd13623-f08d-4204-b32b-3ed10339f85a' User entered 'No (N)'	System	20 Oct 2020 03:55:05
	System	20 Oct 2020 03:55:05

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:04:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 22:04:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-19T22:55:03', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '7fd13623-f08d-4204-b32b-3ed10339f85a' User entered '19 Oct 2020 22:55'	System	20 Oct 2020 03:55:05
	System	20 Oct 2020 03:55:05

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:04:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 22:04:00
User entered '19 Oct 2020 12:00'	System	15 Oct 2020 14:57:38

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:04:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 22:04:00
User entered '20 Oct 2020 11:59'	System	15 Oct 2020 14:57:38

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 22:04:00
Data entry locked.	System	15 Oct 2020 14:57:38
User entered 'Day 6'	System	15 Oct 2020 14:57:38

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:04:12

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 22:04:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-20T23:33:55', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '14d19389-fb21-46f6-8efc-d9b441b227eb' User entered 'None (0)'	System	21 Oct 2020 04:45:56
	System	21 Oct 2020 04:45:56

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:04:12

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 22:04:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-20T23:33:57', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '14d19389-fb21-46f6-8efc-d9b441b227eb' User entered 'None (0)'	System	21 Oct 2020 04:45:56
	System	21 Oct 2020 04:45:56

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:04:12

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 22:04:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-20T23:34:00', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '14d19389-fb21-46f6-8efc-d9b441b227eb' User entered 'None (0)'	System	21 Oct 2020 04:45:56
	System	21 Oct 2020 04:45:56

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:04:12

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 22:04:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-20T23:34:02', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '14d19389-fb21-46f6-8efc-d9b441b227eb' User entered 'None (0)'	System	21 Oct 2020 04:45:56
	System	21 Oct 2020 04:45:56

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:04:12

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 22:04:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-20T23:34:05', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '14d19389-fb21-46f6-8efc-d9b441b227eb' User entered 'None (0)'	System	21 Oct 2020 04:45:56
	System	21 Oct 2020 04:45:56

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:04:12

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 22:04:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-20T23:34:07', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '14d19389-fb21-46f6-8efc-d9b441b227eb' User entered 'None (0)'	System	21 Oct 2020 04:45:56
	System	21 Oct 2020 04:45:56

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:04:12

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)	08 Mar 2021 22:04:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-20T23:45:50', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '14d19389-fb21-46f6-8efc-d9b441b227eb' User entered 'No (N)'	System	21 Oct 2020 04:45:56
	System	21 Oct 2020 04:45:56

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:04:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 22:04:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-20T23:45:54', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '14d19389-fb21-46f6-8efc-d9b441b227eb' User entered '20 Oct 2020 23:45'	System	21 Oct 2020 04:45:56
	System	21 Oct 2020 04:45:56

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:04:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 22:04:00
User entered '20 Oct 2020 12:00'	System	15 Oct 2020 14:57:38

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:04:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 22:04:00
User entered '21 Oct 2020 11:59'	System	15 Oct 2020 14:57:38

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 22:04:00
Data entry locked.	System	15 Oct 2020 14:57:38
User entered 'Day 7'	System	15 Oct 2020 14:57:38

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:04:12

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 22:04:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-21T22:21:56', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '71dfdba9-d164-4098-b2ef-81139404f542'	System	22 Oct 2020 03:22:34
User entered 'None (0)'	System	22 Oct 2020 03:22:34

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:04:12

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 22:04:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-21T22:22:08', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '71dfdba9-d164-4098-b2ef-81139404f542'	System	22 Oct 2020 03:22:34
User entered 'None (0)'	System	22 Oct 2020 03:22:34

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:04:12

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 22:04:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-21T22:22:13', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '71dfdba9-d164-4098-b2ef-81139404f542'	System	22 Oct 2020 03:22:34
User entered 'None (0)'	System	22 Oct 2020 03:22:34

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:04:12

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 22:04:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-21T22:22:17', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '71dfdba9-d164-4098-b2ef-81139404f542'	System	22 Oct 2020 03:22:34
User entered 'None (0)'	System	22 Oct 2020 03:22:34

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:04:12

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 22:04:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-21T22:22:20', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '71dfdba9-d164-4098-b2ef-81139404f542'	System	22 Oct 2020 03:22:34
User entered 'None (0)'	System	22 Oct 2020 03:22:34

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:04:12

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 22:04:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-21T22:22:23', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '71dfdba9-d164-4098-b2ef-81139404f542'	System	22 Oct 2020 03:22:34
User entered 'None (0)'	System	22 Oct 2020 03:22:34

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:04:12

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)	08 Mar 2021 22:04:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-21T22:22:27', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '71dfdba9-d164-4098-b2ef-81139404f542'	System	22 Oct 2020 03:22:34
User entered 'No (N)'	System	22 Oct 2020 03:22:34

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:04:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 22:04:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-21T22:22:31', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '71dfdba9-d164-4098-b2ef-81139404f542'	System	22 Oct 2020 03:22:34
User entered '21 Oct 2020 22:22'	System	22 Oct 2020 03:22:34

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:04:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 22:04:00
User entered '21 Oct 2020 12:00'	System	15 Oct 2020 14:57:38

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:04:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	08 Mar 2021 22:04:00
User entered '22 Oct 2020 11:59'	System	15 Oct 2020 14:57:38

US3322329

Folder: Diary Dose 2 (1)

Form: Redness_Day(8)

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
Data entry locked.	System	21 Oct 2020 04:33:53
User entered 'Day 8'	System	21 Oct 2020 04:33:53

US3322329

Folder: Diary Dose 2 (1)

Form: Redness_Day(8)

Generated On: 09 Jun 2021 17:04:12

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-22T13:21:47', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '59a1a704-5597-4a86-b246-2a6b19c2a94f' User entered 'No (N)'	System	22 Oct 2020 18:21:58
	System	22 Oct 2020 18:21:58

US3322329

Folder: Diary Dose 2 (1)

Form: Redness_Day(8)

Generated On: 09 Jun 2021 17:04:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-22T13:21:56', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '59a1a704-5597-4a86-b246-2a6b19c2a94f' User entered '22 Oct 2020 13:21'	System	22 Oct 2020 18:21:58
	System	22 Oct 2020 18:21:58

US3322329

Folder: Diary Dose 2 (1)

Form: Redness_Day(8)

Generated On: 09 Jun 2021 17:04:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
User entered '22 Oct 2020 12:00'	System	21 Oct 2020 04:33:53

US3322329

Folder: Diary Dose 2 (1)

Form: Redness_Day(8)

Generated On: 09 Jun 2021 17:04:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
User entered '23 Oct 2020 11:59'	System	21 Oct 2020 04:33:53

US3322329

Folder: Diary Dose 2 (1)

Form: Swelling_Day(8)

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
Data entry locked.	System	21 Oct 2020 04:33:53
User entered 'Day 8'	System	21 Oct 2020 04:33:53

US3322329

Folder: Diary Dose 2 (1)

Form: Swelling_Day(8)

Generated On: 09 Jun 2021 17:04:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-22T13:22:02', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '7b932203-7f17-47ac-aa96-4e2caefc485a' User entered 'Yes (Y)'	System	22 Oct 2020 18:22:22
	System	22 Oct 2020 18:22:22

US3322329

Folder: Diary Dose 2 (1)

Form: Swelling_Day(8)

Generated On: 09 Jun 2021 17:04:12

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-22T13:22:13', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '7b932203-7f17-47ac-aa96-4e2caefc485a' User entered '25'	System	22 Oct 2020 18:22:22
	System	22 Oct 2020 18:22:22

US3322329

Folder: Diary Dose 2 (1)

Form: Swelling_Day(8)

Generated On: 09 Jun 2021 17:04:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-22T13:22:21', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '7b932203-7f17-47ac-aa96-4e2caefc485a' User entered '22 Oct 2020 13:22'	System	22 Oct 2020 18:22:22
	System	22 Oct 2020 18:22:22

US3322329

Folder: Diary Dose 2 (1)

Form: Swelling_Day(8)

Generated On: 09 Jun 2021 17:04:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
User entered '22 Oct 2020 12:00'	System	21 Oct 2020 04:33:53

US3322329

Folder: Diary Dose 2 (1)

Form: Swelling_Day(8)

Generated On: 09 Jun 2021 17:04:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
User entered '23 Oct 2020 11:59'	System	21 Oct 2020 04:33:53

US3322329

Folder: Diary Dose 2 (1)

Form: Swelling_Day(9)

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
Data entry locked.	System	22 Oct 2020 03:21:51
User entered 'Day 9'	System	22 Oct 2020 03:21:51

US3322329

Folder: Diary Dose 2 (1)

Form: Swelling_Day(9)

Generated On: 09 Jun 2021 17:04:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-23T14:21:25', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'e3ee5167-511b-4239-8ebc-30254a27a088'	System	23 Oct 2020 19:21:32
User entered 'No (N)'	System	23 Oct 2020 19:21:32

US3322329

Folder: Diary Dose 2 (1)

Form: Swelling_Day(9)

Generated On: 09 Jun 2021 17:04:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-23T14:21:29', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'e3ee5167-511b-4239-8ebc-30254a27a088' User entered '23 Oct 2020 14:21'	System	23 Oct 2020 19:21:32
	System	23 Oct 2020 19:21:32

US3322329

Folder: Diary Dose 2 (1)

Form: Swelling_Day(9)

Generated On: 09 Jun 2021 17:04:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
User entered '23 Oct 2020 12:00'	System	22 Oct 2020 03:21:51

US3322329

Folder: Diary Dose 2 (1)

Form: Swelling_Day(9)

Generated On: 09 Jun 2021 17:04:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
User entered '24 Oct 2020 11:59'	System	22 Oct 2020 03:21:51

US3322329

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
Data entry locked.	System	21 Oct 2020 04:33:53
User entered 'Day 8'	System	21 Oct 2020 04:33:53

US3322329

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:04:12

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 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-22T13:22:24', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '004b8aa7-6d8f-4aae-802b-ff1f5796bdd1' User entered 'No (N)'	System	22 Oct 2020 18:22:31
	System	22 Oct 2020 18:22:31

US3322329

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:04:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-22T13:22:27', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '004b8aa7-6d8f-4aae-802b-ff1f5796bdd1' User entered '22 Oct 2020 13:22'	System	22 Oct 2020 18:22:31
	System	22 Oct 2020 18:22:31

US3322329

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:04:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
User entered '22 Oct 2020 12:00'	System	21 Oct 2020 04:33:53

US3322329

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:04:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
User entered '23 Oct 2020 11:59'	System	21 Oct 2020 04:33:53

US3322329

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
Data entry locked.	System	22 Oct 2020 03:21:51
User entered 'Day 9'	System	22 Oct 2020 03:21:51

US3322329

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 17:04:12

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 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-23T14:21:34', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '00b0a97c-6ac0-4383-90b1-0a507d3abada' User entered 'No (N)'	System	23 Oct 2020 19:21:42
	System	23 Oct 2020 19:21:42

US3322329

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 17:04:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-23T14:21:37', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '00b0a97c-6ac0-4383-90b1-0a507d3abada' User entered '23 Oct 2020 14:21'	System	23 Oct 2020 19:21:42
	System	23 Oct 2020 19:21:42

US3322329

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 17:04:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
User entered '23 Oct 2020 12:00'	System	22 Oct 2020 03:21:51

US3322329

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 17:04:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
User entered '24 Oct 2020 11:59'	System	22 Oct 2020 03:21:51

US3322329

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:04:12

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
DataPoint Verified.		03 Mar 2021 21:47:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'Yes (Y)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	23 Oct 2020 14:15:57

US3322329

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:04:12

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
DataPoint Verified.		03 Mar 2021 21:47:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered '22 Oct 2020'	(b) (4) Elisa Moralez (b) (4) (b) (4)	23 Oct 2020 14:15:57

US3322329

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:04:12

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
DataPoint Verified.		03 Mar 2021 21:47:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	23 Oct 2020 14:15:57

US3322329

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:04:12

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
DataPoint Verified.		03 Mar 2021 21:47:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered empty.	(b) (4) Elisa Moralez (b) (4) (b) (4)	23 Oct 2020 14:15:57

US3322329

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:04:12

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
DataPoint Verified.		03 Mar 2021 21:47:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'Yes (Y)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	23 Oct 2020 14:15:43

US3322329

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:04:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
User entered 'I'	System	23 Oct 2020 14:15:43

US3322329

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:04:12

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
DataPoint Verified.		03 Mar 2021 21:47:53
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'Yes (Y)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	29 Oct 2020 15:10:01

US3322329

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:04:12

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
DataPoint Verified.		03 Mar 2021 21:47:53
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered '29 Oct 2020'	(b) (4) Elisa Moralez (b) (4) (b) (4)	29 Oct 2020 15:10:01

US3322329

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:04:12

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
DataPoint Verified.		03 Mar 2021 21:47:53
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	29 Oct 2020 15:10:01

US3322329

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:04:12

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
DataPoint Verified.		03 Mar 2021 21:47:53
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered empty.	(b) (4) Elisa Moralez (b) (4) (b) (4)	29 Oct 2020 15:10:01

US3322329

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:04:12

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
DataPoint Verified.		03 Mar 2021 21:47:59
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'Yes (Y)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	29 Oct 2020 15:10:03

US3322329

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:04:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
User entered 'I'	System	29 Oct 2020 15:10:03

US3322329

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:04:12

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
DataPoint Verified.		03 Mar 2021 21:48:16
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'Yes (Y)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	06 Nov 2020 17:39:31

US3322329

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:04:12

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
DataPoint Verified.		03 Mar 2021 21:48:16
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered '5 Nov 2020'	(b) (4) Elisa Moralez (b) (4) (b) (4)	06 Nov 2020 17:39:31

US3322329

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:04:12

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
DataPoint Verified.		03 Mar 2021 21:48:16
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	06 Nov 2020 17:39:31

US3322329

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:04:12

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
DataPoint Verified.		03 Mar 2021 21:48:16
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered empty.	(b) (4) Elisa Moralez (b) (4) (b) (4)	06 Nov 2020 17:39:31

US3322329

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:04:12

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
DataPoint Verified.		03 Mar 2021 21:48:19
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'Yes (Y)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	06 Nov 2020 17:39:22

US3322329

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:04:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
User entered 'I'	System	06 Nov 2020 17:39:22

US3322329

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:04:12

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
DataPoint Verified.		03 Mar 2021 21:48:44
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'Yes (Y)'	(b) (4) Moez Talpur (b) (4) (b) (4)	17 Nov 2020 16:54:52

US3322329

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:04:12

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
DataPoint Verified.		03 Mar 2021 21:48:44
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered '17 Nov 2020'	(b) (4) Moez Talpur (b) (4) (b) (4)	17 Nov 2020 16:54:52

US3322329

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:04:12

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
DataPoint Verified.		03 Mar 2021 21:48:44
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'Clinic (Clinic)'	(b) (4) Moez Talpur (b) (4) (b) (4)	17 Nov 2020 16:54:52

US3322329

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:04:12

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
User entered 'VISIT3'	System	17 Nov 2020 16:54:52

US3322329

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:04:12

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
DataPoint Verified.		03 Mar 2021 21:49:55
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'Yes (Y)'	(b) (4) Moez Talpur (b) (4) (b) (4)	17 Nov 2020 16:57:22

US3322329

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:04:12

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
DataPoint Verified.		03 Mar 2021 21:49:55
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered '17 Nov 2020'	(b) (4) Moez Talpur (b) (4) (b) (4)	17 Nov 2020 16:57:22

US3322329

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:04:12

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
DataPoint Verified.		03 Mar 2021 21:49:55
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered '09:30'	(b) (4)	
	Moez Talpur (b) (4)	17 Nov 2020 16:57:22
	(b) (4)	

US3322329

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:04:12

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
User entered '17 Nov 2020 09:30'	System	17 Nov 2020 16:57:22

US3322329

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:04:12

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
DataPoint Verified.		03 Mar 2021 21:49:55
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User closed query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:32:36
Query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS per source' (Site from System).	Frances Saubon (b) (4) (b) (4)	17 Nov 2020 17:13:24
User opened query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	17 Nov 2020 16:57:22
User entered '96.6' F	Moez Talpur (b) (4) (b) (4)	17 Nov 2020 16:57:22

US3322329

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:04:12

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
DataPoint Verified.		03 Mar 2021 21:49:55
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'Oral (Oral)'	(b) (4) Moez Talpur (b) (4) (b) (4)	17 Nov 2020 16:57:22

US3322329

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:04:12

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
DataPoint Verified.		03 Mar 2021 21:49:55
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered empty.	(b) (4)	
	Moez Talpur (b) (4)	17 Nov 2020 16:57:22
	(b) (4)	

US3322329

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:04:12

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
DataPoint Verified.		03 Mar 2021 21:49:55
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered '63'	(b) (4) Moez Talpur (b) (4) (b) (4)	17 Nov 2020 16:57:22

US3322329

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:04:12

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
User entered 'bpm'	System	17 Nov 2020 16:57:22

US3322329

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:04:12

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
DataPoint Verified.		03 Mar 2021 21:49:55
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered '17'	(b) (4) Moez Talpur (b) (4) (b) (4)	17 Nov 2020 16:57:22

US3322329

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:04:12

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
User entered 'breaths/min'	System	17 Nov 2020 16:57:22

US3322329

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:04:12

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
DataPoint Verified.		03 Mar 2021 21:49:55
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered '128'	(b) (4) Moez Talpur (b) (4) (b) (4)	17 Nov 2020 16:57:22

US3322329

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:04:12

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
User entered 'mmHg'	System	17 Nov 2020 16:57:22

US3322329

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:04:12

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
DataPoint Verified.		03 Mar 2021 21:49:55
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered '90'	(b) (4) Moez Talpur (b) (4) (b) (4)	17 Nov 2020 16:57:22

US3322329

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:04:12

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
User entered 'mmHg'	System	17 Nov 2020 16:57:22

US3322329

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:04:12

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51

US3322329

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:04:12

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51

US3322329

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:04:12

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
DataPoint Verified.		03 Mar 2021 21:50:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'Yes (Y)'	(b) (4) Moez Talpur (b) (4) (b) (4)	17 Nov 2020 16:58:24

US3322329

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:04:12

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
DataPoint Verified.		03 Mar 2021 21:50:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered '17 Nov 2020'	(b) (4) Moez Talpur (b) (4) (b) (4)	17 Nov 2020 16:58:24

US3322329

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:04:12

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
DataPoint Verified.		03 Mar 2021 21:50:39
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'Yes (Y)'	(b) (4) Moez Talpur (b) (4) (b) (4)	17 Nov 2020 16:58:37

US3322329

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:04:12

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
DataPoint Verified.		03 Mar 2021 21:50:39
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered '17 Nov 2020'	(b) (4) Moez Talpur (b) (4) (b) (4)	17 Nov 2020 16:58:37

US3322329

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:04:12

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
DataPoint Verified.		03 Mar 2021 21:50:39
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered '10:24'	(b) (4) Moez Talpur (b) (4) (b) (4)	17 Nov 2020 16:58:37

US3322329

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:04:12

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
User entered '17 Nov 2020 10:24'	System	17 Nov 2020 16:58:37

US3322329

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:04:12

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
DataPoint Verified.		03 Mar 2021 21:50:43
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'Yes (Y)'	(b) (4) Moez Talpur (b) (4) (b) (4)	17 Nov 2020 16:58:45

US3322329

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:04:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
User entered 'I'	System	17 Nov 2020 16:58:45

US3322329

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
Data entry locked.	System	12 Sep 2020 17:10:21
User entered 'Day 64'	System	12 Sep 2020 17:10:21

US3322329

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[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 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-11-12T09:07:19', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '513ea189-1891-4540-ac53-a431a61c802a' User entered 'No (N)'	System	12 Nov 2020 15:07:32
	System	12 Nov 2020 15:07:32

US3322329

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

Have you been exposed to someone with 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 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-11-12T09:07:24', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '513ea189-1891-4540-ac53-a431a61c802a' User entered 'No (N)'	System	12 Nov 2020 15:07:32
	System	12 Nov 2020 15:07:32

US3322329

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-11-12T09:07:27', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '513ea189-1891-4540-ac53-a431a61c802a' User entered '12 Nov 2020 09:07:27'	System	12 Nov 2020 15:07:32
	System	12 Nov 2020 15:07:32

US3322329

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
Data entry locked.	System	12 Sep 2020 17:10:21
User entered '12 Nov 2020 00:01'	System	12 Sep 2020 17:10:21

US3322329

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
Data entry locked.	System	12 Sep 2020 17:10:21
User entered '16 Nov 2020 23:59'	System	12 Sep 2020 17:10:21

US3322329

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
Data entry locked.	System	12 Sep 2020 17:10:21
User entered 'Day 71'	System	12 Sep 2020 17:10:21

US3322329

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[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 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-11-19T14:42:30', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '06e34833-2611-4a1d-9a36-b6a67149d9fb' User entered 'No (N)'	System	19 Nov 2020 20:42:52
	System	19 Nov 2020 20:42:52

US3322329

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

Have you been exposed to someone with 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 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-11-19T14:42:34', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '06e34833-2611-4a1d-9a36-b6a67149d9fb' User entered 'No (N)'	System	19 Nov 2020 20:42:52
	System	19 Nov 2020 20:42:52

US3322329

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-11-19T14:42:48', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '06e34833-2611-4a1d-9a36-b6a67149d9fb' User entered '19 Nov 2020 14:42:48'	System	19 Nov 2020 20:42:52
	System	19 Nov 2020 20:42:52

US3322329

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
Data entry locked.	System	12 Sep 2020 17:10:21
User entered '19 Nov 2020 00:01'	System	12 Sep 2020 17:10:21

US3322329

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:00:07
Data entry locked.	System	12 Sep 2020 17:10:21
User entered '23 Nov 2020 23:59'	System	12 Sep 2020 17:10:21

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

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 (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-11-23T06:45:28', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'ba4144a5-c120-459c-8923-9ffa53c8ce07'	System	23 Nov 2020 12:45:52
User entered 'No (N)'	System	23 Nov 2020 12:45:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

Have you been exposed to someone with 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 (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-11-23T06:45:42', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'ba4144a5-c120-459c-8923-9ffa53c8ce07'	System	23 Nov 2020 12:45:52
User entered 'No (N)'	System	23 Nov 2020 12:45:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-11-23T06:45:49', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'ba4144a5-c120-459c-8923-9ffa53c8ce07'	System	23 Nov 2020 12:45:52
User entered '23 Nov 2020 06:45:49'	System	23 Nov 2020 12:45:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '23 Nov 2020 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '27 Nov 2020 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[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 (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-12-03T07:40:58', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '1c115b84-a1e6-4f56-bc00-522f435946ca' User entered 'No (N)'	System	03 Dec 2020 13:41:16
	System	03 Dec 2020 13:41:16

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

Have you been exposed to someone with 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 (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-12-03T07:41:05', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '1c115b84-a1e6-4f56-bc00-522f435946ca' User entered 'No (N)'	System	03 Dec 2020 13:41:16
	System	03 Dec 2020 13:41:16

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-12-03T07:41:13', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '1c115b84-a1e6-4f56-bc00-522f435946ca' User entered '03 Dec 2020 07:41:13'	System	03 Dec 2020 13:41:16
	System	03 Dec 2020 13:41:16

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '30 Nov 2020 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '04 Dec 2020 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[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 (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-12-10T08:56:50', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'd0a8570f-f236-4484-92b5-3061e3a33933' User entered 'No (N)'	System	10 Dec 2020 14:57:01
	System	10 Dec 2020 14:57:01

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Have you been exposed to someone with 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 (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-12-10T08:56:53', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'd0a8570f-f236-4484-92b5-3061e3a33933'	System	10 Dec 2020 14:57:01
User entered 'No (N)'	System	10 Dec 2020 14:57:01

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-12-10T08:56:56', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'd0a8570f-f236-4484-92b5-3061e3a33933' User entered '10 Dec 2020 08:56:56'	System	10 Dec 2020 14:57:01
	System	10 Dec 2020 14:57:01

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '07 Dec 2020 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '11 Dec 2020 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[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 (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-12-16T14:32:50', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '3534b73d-cb97-4000-bdf4-3e4f5dd95a00'	System	16 Dec 2020 20:33:02
User entered 'No (N)'	System	16 Dec 2020 20:33:02

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

Have you been exposed to someone with 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 (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-12-16T14:32:56', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '3534b73d-cb97-4000-bdf4-3e4f5dd95a00'	System	16 Dec 2020 20:33:02
User entered 'No (N)'	System	16 Dec 2020 20:33:02

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-12-16T14:33:00', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '3534b73d-cb97-4000-bdf4-3e4f5dd95a00' User entered '16 Dec 2020 14:33:00'	System	16 Dec 2020 20:33:02
	System	16 Dec 2020 20:33:02

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '14 Dec 2020 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '18 Dec 2020 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[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 (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-12-21T08:34:21', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'd5a211de-cca2-43dd-872c-25f7dce543df' User entered 'No (N)'	System	21 Dec 2020 14:34:43
	System	21 Dec 2020 14:34:43

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

Have you been exposed to someone with 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 (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-12-21T08:34:30', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'd5a211de-cca2-43dd-872c-25f7dce543df' User entered 'No (N)'	System	21 Dec 2020 14:34:43
	System	21 Dec 2020 14:34:43

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-12-21T08:34:40', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'd5a211de-cca2-43dd-872c-25f7dce543df' User entered '21 Dec 2020 08:34:40'	System	21 Dec 2020 14:34:43
	System	21 Dec 2020 14:34:43

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '21 Dec 2020 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '25 Dec 2020 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[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 (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-12-31T09:06:25', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '9db374ea-b847-46a2-bd1f-3d042bdeebe3' User entered 'No (N)'	System	31 Dec 2020 15:06:41
	System	31 Dec 2020 15:06:41

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

Have you been exposed to someone with 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 (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-12-31T09:06:32', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '9db374ea-b847-46a2-bd1f-3d042bdeebe3' User entered 'No (N)'	System	31 Dec 2020 15:06:41
	System	31 Dec 2020 15:06:41

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-12-31T09:06:37', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '9db374ea-b847-46a2-bd1f-3d042bdeeb3' User entered '31 Dec 2020 09:06:37'	System	31 Dec 2020 15:06:41
	System	31 Dec 2020 15:06:41

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '28 Dec 2020 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '01 Jan 2021 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[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 (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2021-01-05T10:28:51', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '63317d5b-250a-4f59-95ca-9f5041701906' User entered 'No (N)'	System	05 Jan 2021 16:29:07
	System	05 Jan 2021 16:29:07

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

Have you been exposed to someone with 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 (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2021-01-05T10:28:58', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '63317d5b-250a-4f59-95ca-9f5041701906'	System	05 Jan 2021 16:29:07
User entered 'No (N)'	System	05 Jan 2021 16:29:07

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2021-01-05T10:29:04', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '63317d5b-250a-4f59-95ca-9f5041701906' User entered '05 Jan 2021 10:29:04'	System	05 Jan 2021 16:29:07
	System	05 Jan 2021 16:29:07

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '04 Jan 2021 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '08 Jan 2021 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[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 (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2021-01-11T08:50:01', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '901bb129-e76b-41be-b76a-9c04ace58d7a' User entered 'No (N)'	System	11 Jan 2021 14:50:21
	System	11 Jan 2021 14:50:21

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

Have you been exposed to someone with 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 (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2021-01-11T08:50:13', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '901bb129-e76b-41be-b76a-9c04ace58d7a' User entered 'No (N)'	System	11 Jan 2021 14:50:21
	System	11 Jan 2021 14:50:21

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2021-01-11T08:50:17', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '901bb129-e76b-41be-b76a-9c04ace58d7a' User entered '11 Jan 2021 08:50:17'	System	11 Jan 2021 14:50:21
	System	11 Jan 2021 14:50:21

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '11 Jan 2021 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '15 Jan 2021 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[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 (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2021-01-19T15:26:17', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '44ff05a1-b6ef-47c3-bae5-321c9bc7fa5d' User entered 'No (N)'	System	19 Jan 2021 21:26:30
	System	19 Jan 2021 21:26:30

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

Have you been exposed to someone with 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 (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2021-01-19T15:26:23', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '44ff05a1-b6ef-47c3-bae5-321c9bc7fa5d' User entered 'No (N)'	System	19 Jan 2021 21:26:30
	System	19 Jan 2021 21:26:30

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2021-01-19T15:26:26', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '44ff05a1-b6ef-47c3-bae5-321c9bc7fa5d' User entered '19 Jan 2021 15:26:26'	System	19 Jan 2021 21:26:30
	System	19 Jan 2021 21:26:30

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '18 Jan 2021 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '22 Jan 2021 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[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 (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2021-01-25T00:01:42', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'b69ddd1a-3af6-441c-afed-c92c32b44a82'	System	25 Jan 2021 06:01:54
User entered 'No (N)'	System	25 Jan 2021 06:01:54

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

Have you been exposed to someone with 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 (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2021-01-25T00:01:48', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'b69ddd1a-3af6-441c-afed-c92c32b44a82'	System	25 Jan 2021 06:01:54
User entered 'No (N)'	System	25 Jan 2021 06:01:54

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2021-01-25T00:01:51', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'b69ddd1a-3af6-441c-afed-c92c32b44a82' User entered '25 Jan 2021 00:01:51'	System	25 Jan 2021 06:01:54
	System	25 Jan 2021 06:01:54

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '25 Jan 2021 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '29 Jan 2021 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[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 (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2021-02-03T12:00:43', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'f8f0da0b-d6c0-450f-afb7-c87f11170640'	System	03 Feb 2021 18:01:53
User entered 'No (N)'	System	03 Feb 2021 18:01:53

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

Have you been exposed to someone with 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 (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2021-02-03T12:00:48', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'f8f0da0b-d6c0-450f-afb7-c87f11170640'	System	03 Feb 2021 18:01:53
User entered 'No (N)'	System	03 Feb 2021 18:01:53

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2021-02-03T12:00:53', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'f8f0da0b-d6c0-450f-afb7-c87f11170640'	System	03 Feb 2021 18:01:53
User entered '03 Feb 2021 12:00:53'	System	03 Feb 2021 18:01:53

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '01 Feb 2021 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '05 Feb 2021 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[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 (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2021-02-08T00:01:48', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '3ba5f202-7306-4550-adbd-680f9d0c890e' User entered 'No (N)'	System	08 Feb 2021 06:02:01
	System	08 Feb 2021 06:02:01

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

Have you been exposed to someone with 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 (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2021-02-08T00:01:53', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '3ba5f202-7306-4550-adbd-680f9d0c890e' User entered 'No (N)'	System	08 Feb 2021 06:02:01

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2021-02-08T00:01:58', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '3ba5f202-7306-4550-adbd-680f9d0c890e' User entered '08 Feb 2021 00:01:58'	System	08 Feb 2021 06:02:01
	System	08 Feb 2021 06:02:01

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '08 Feb 2021 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '12 Feb 2021 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '15 Feb 2021 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '19 Feb 2021 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[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 (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2021-02-22T15:59:59', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '4315f1a5-689d-4727-aac1-e375637704b0' User entered 'No (N)'	System	22 Feb 2021 22:00:48
	System	22 Feb 2021 22:00:48

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

Have you been exposed to someone with 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 (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2021-02-22T16:00:05', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '4315f1a5-689d-4727-aac1-e375637704b0' User entered 'Yes (Y)'	System	22 Feb 2021 22:00:48
	System	22 Feb 2021 22:00:48

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Please 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 (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2021-02-22T16:00:14', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '4315f1a5-689d-4727-aac1-e375637704b0'	System	22 Feb 2021 22:00:48
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	22 Feb 2021 22:00:48

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2021-02-22T16:00:32', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '4315f1a5-689d-4727-aac1-e375637704b0' User entered '22 Feb 2021 16:00:32'	System	22 Feb 2021 22:00:48
	System	22 Feb 2021 22:00:48

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '22 Feb 2021 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '26 Feb 2021 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[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 (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2021-03-02T11:18:29-06:00', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '61b66cfd-99c0-434c-b471-6adc0e21a76e' User entered 'No (N)'	System	02 Mar 2021 17:21:33
	System	02 Mar 2021 17:21:33

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

Have you been exposed to someone with 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 (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2021-03-02T11:18:31-06:00', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '61b66cfd-99c0-434c-b471-6adc0e21a76e' User entered 'No (N)'	System	02 Mar 2021 17:21:33
	System	02 Mar 2021 17:21:33

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2021-03-02T11:18:35-06:00', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '61b66cfd-99c0-434c-b471-6adc0e21a76e' User entered '02 Mar 2021 17:18:35'	System	02 Mar 2021 17:21:33
	System	02 Mar 2021 17:21:33

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '01 Mar 2021 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '05 Mar 2021 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[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 (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2021-03-08T12:26:29-06:00', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '195804cb-a847-442b-af17-1ab5a3600c1c'	System	08 Mar 2021 18:26:39
User entered 'No (N)'	System	08 Mar 2021 18:26:39

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

Have you been exposed to someone with 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 (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2021-03-08T12:26:32-06:00', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '195804cb-a847-442b-af17-1ab5a3600c1c'	System	08 Mar 2021 18:26:39
User entered 'No (N)'	System	08 Mar 2021 18:26:39

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2021-03-08T12:26:36-06:00', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '195804cb-a847-442b-af17-1ab5a3600c1c' User entered '08 Mar 2021 18:26:36'	System	08 Mar 2021 18:26:39
	System	08 Mar 2021 18:26:39

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '08 Mar 2021 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '12 Mar 2021 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[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 (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2021-03-16T12:51:48-05:00', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'b296cad8-81f2-4928-8159-e25b44e4d33d'	System	16 Mar 2021 17:51:58
User entered 'No (N)'	System	16 Mar 2021 17:51:58

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Have you been exposed to someone with 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 (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2021-03-16T12:51:51-05:00', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'b296cad8-81f2-4928-8159-e25b44e4d33d'	System	16 Mar 2021 17:51:58
User entered 'No (N)'	System	16 Mar 2021 17:51:58

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2021-03-16T12:51:55-05:00', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'b296cad8-81f2-4928-8159-e25b44e4d33d' User entered '16 Mar 2021 17:51:55'	System	16 Mar 2021 17:51:58
	System	16 Mar 2021 17:51:58

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '15 Mar 2021 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '19 Mar 2021 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

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 (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2021-03-22T00:02:24-05:00', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '7f611e4c-aca1-470b-9d7b-933e4cc79aad'	System	22 Mar 2021 05:02:43
User entered 'No (N)'	System	22 Mar 2021 05:02:43

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

Have you been exposed to someone with 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 (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2021-03-22T00:02:33-05:00', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '7f611e4c-aca1-470b-9d7b-933e4cc79aad'	System	22 Mar 2021 05:02:43
User entered 'No (N)'	System	22 Mar 2021 05:02:43

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2021-03-22T00:02:38-05:00', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '7f611e4c-aca1-470b-9d7b-933e4cc79aad'	System	22 Mar 2021 05:02:43
User entered '22 Mar 2021 05:02:38'	System	22 Mar 2021 05:02:43

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '22 Mar 2021 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '26 Mar 2021 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[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 (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2021-03-29T10:40:37-05:00', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'c7e4a343-d7a8-4814-b0d1-a04a4fa5cb9a'	System	29 Mar 2021 15:40:47
User entered 'No (N)'	System	29 Mar 2021 15:40:47

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

Have you been exposed to someone with 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 (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2021-03-29T10:40:40-05:00', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'c7e4a343-d7a8-4814-b0d1-a04a4fa5cb9a'	System	29 Mar 2021 15:40:47
User entered 'No (N)'	System	29 Mar 2021 15:40:47

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2021-03-29T10:40:44-05:00', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'c7e4a343-d7a8-4814-b0d1-a04a4fa5cb9a' User entered '29 Mar 2021 15:40:44'	System	29 Mar 2021 15:40:47
	System	29 Mar 2021 15:40:47

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '29 Mar 2021 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '02 Apr 2021 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[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 (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2021-04-05T00:02:28-05:00', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '529be56b-d3f9-4f7c-baa5-12e8fc225b04'	System	05 Apr 2021 13:52:56
User entered 'Yes (Y)'	System	05 Apr 2021 13:52:56

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

Have you been exposed to someone with 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 (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2021-04-05T00:02:44-05:00', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '529be56b-d3f9-4f7c-baa5-12e8fc225b04'	System	05 Apr 2021 13:52:56
User entered 'No (N)'	System	05 Apr 2021 13:52:56

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[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 (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2021-04-05T00:02:55-05:00', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '529be56b-d3f9-4f7c-baa5-12e8fc225b04'	System	05 Apr 2021 13:52:56
User entered 'Yes (Y)'	System	05 Apr 2021 13:52:56

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2021-04-05T08:52:00-05:00', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '529be56b-d3f9-4f7c-baa5-12e8fc225b04'	System	05 Apr 2021 13:52:56
User entered '1'	System	05 Apr 2021 13:52:56

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2021-04-05T08:52:00-05:00', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '529be56b-d3f9-4f7c-baa5-12e8fc225b04'	System	05 Apr 2021 13:52:56
User entered '1'	System	05 Apr 2021 13:52:56

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2021-04-05T08:52:00-05:00', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '529be56b-d3f9-4f7c-baa5-12e8fc225b04'	System	05 Apr 2021 13:52:56
User entered '0'	System	05 Apr 2021 13:52:56

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2021-04-05T08:52:00-05:00', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '529be56b-d3f9-4f7c-baa5-12e8fc225b04'	System	05 Apr 2021 13:52:56
User entered '0'	System	05 Apr 2021 13:52:56

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2021-04-05T08:52:00-05:00', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '529be56b-d3f9-4f7c-baa5-12e8fc225b04'	System	05 Apr 2021 13:52:56
User entered '0'	System	05 Apr 2021 13:52:56

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2021-04-05T08:52:00-05:00', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '529be56b-d3f9-4f7c-baa5-12e8fc225b04'	System	05 Apr 2021 13:52:56
User entered '1'	System	05 Apr 2021 13:52:56

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2021-04-05T08:52:00-05:00', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '529be56b-d3f9-4f7c-baa5-12e8fc225b04' User entered '0'	System	05 Apr 2021 13:52:56
	System	05 Apr 2021 13:52:56

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2021-04-05T08:52:00-05:00', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '529be56b-d3f9-4f7c-baa5-12e8fc225b04'	System	05 Apr 2021 13:52:56
User entered '0'	System	05 Apr 2021 13:52:56

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2021-04-05T08:52:00-05:00', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '529be56b-d3f9-4f7c-baa5-12e8fc225b04'	System	05 Apr 2021 13:52:56
User entered '0'	System	05 Apr 2021 13:52:56

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2021-04-05T08:52:00-05:00', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '529be56b-d3f9-4f7c-baa5-12e8fc225b04'	System	05 Apr 2021 13:52:56
User entered '0'	System	05 Apr 2021 13:52:56

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2021-04-05T08:52:00-05:00', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '529be56b-d3f9-4f7c-baa5-12e8fc225b04'	System	05 Apr 2021 13:52:56
User entered '0'	System	05 Apr 2021 13:52:56

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2021-04-05T08:52:00-05:00', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '529be56b-d3f9-4f7c-baa5-12e8fc225b04'	System	05 Apr 2021 13:52:56
User entered '0'	System	05 Apr 2021 13:52:56

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2021-04-05T08:52:00-05:00', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '529be56b-d3f9-4f7c-baa5-12e8fc225b04'	System	05 Apr 2021 13:52:56
User entered '0'	System	05 Apr 2021 13:52:56

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2021-04-05T08:52:00-05:00', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '529be56b-d3f9-4f7c-baa5-12e8fc225b04'	System	05 Apr 2021 13:52:56
User entered '0'	System	05 Apr 2021 13:52:56

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2021-04-05T08:52:00-05:00', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '529be56b-d3f9-4f7c-baa5-12e8fc225b04'	System	05 Apr 2021 13:52:56
User entered '1'	System	05 Apr 2021 13:52:56

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2021-04-05T08:52:00-05:00', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '529be56b-d3f9-4f7c-baa5-12e8fc225b04' User entered '0'	System	05 Apr 2021 13:52:56
	System	05 Apr 2021 13:52:56

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2021-04-05T08:52:00-05:00', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '529be56b-d3f9-4f7c-baa5-12e8fc225b04'	System	05 Apr 2021 13:52:56
User entered '0'	System	05 Apr 2021 13:52:56

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Please 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 (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2021-04-05T08:52:04-05:00', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '529be56b-d3f9-4f7c-baa5-12e8fc225b04'	System	05 Apr 2021 13:52:56
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	05 Apr 2021 13:52:56

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[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 (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2021-04-05T08:52:09-05:00', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '529be56b-d3f9-4f7c-baa5-12e8fc225b04'	System	05 Apr 2021 13:52:56
User entered 'Yes (Y)'	System	05 Apr 2021 13:52:56

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

Please 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 (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2021-04-05T08:52:13-05:00', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '529be56b-d3f9-4f7c-baa5-12e8fc225b04'	System	05 Apr 2021 13:52:56
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	05 Apr 2021 13:52:56

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2021-04-05T08:52:47-05:00', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '529be56b-d3f9-4f7c-baa5-12e8fc225b04'	System	05 Apr 2021 13:52:56
User entered '05 Apr 2021 13:52:47'	System	05 Apr 2021 13:52:56

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '05 Apr 2021 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '09 Apr 2021 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

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 (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2021-04-12T06:51:30-05:00', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '7e9adc18-4a76-4ba8-b351-b2df634ae5e7'	System	12 Apr 2021 11:51:41
User entered 'No (N)'	System	12 Apr 2021 11:51:41

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

Have you been exposed to someone with 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 (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2021-04-12T06:51:33-05:00', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '7e9adc18-4a76-4ba8-b351-b2df634ae5e7'	System	12 Apr 2021 11:51:41
User entered 'No (N)'	System	12 Apr 2021 11:51:41

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2021-04-12T06:51:37-05:00', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '7e9adc18-4a76-4ba8-b351-b2df634ae5e7'	System	12 Apr 2021 11:51:41
User entered '12 Apr 2021 11:51:37'	System	12 Apr 2021 11:51:41

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '12 Apr 2021 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '16 Apr 2021 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[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 (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2021-04-19T00:03:50-05:00', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '23be2959-288a-4ab6-a8d4-1ec36c93a010'	System	19 Apr 2021 05:03:59
User entered 'No (N)'	System	19 Apr 2021 05:03:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

Have you been exposed to someone with 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 (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2021-04-19T00:03:53-05:00', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '23be2959-288a-4ab6-a8d4-1ec36c93a010'	System	19 Apr 2021 05:03:59
User entered 'No (N)'	System	19 Apr 2021 05:03:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2021-04-19T00:03:57-05:00', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '23be2959-288a-4ab6-a8d4-1ec36c93a010'	System	19 Apr 2021 05:03:59
User entered '19 Apr 2021 00:03:57'	System	19 Apr 2021 05:03:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '19 Apr 2021 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '23 Apr 2021 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[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 (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2021-04-26T13:40:39-05:00', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'ef231b1f-9544-4fff-839b-b1a70767812d' User entered 'No (N)'	System	26 Apr 2021 18:40:48

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

Have you been exposed to someone with 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 (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2021-04-26T13:40:41-05:00', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'ef231b1f-9544-4fff-839b-b1a70767812d' User entered 'No (N)'	System	26 Apr 2021 18:40:48

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2021-04-26T13:40:44-05:00', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'ef231b1f-9544-4fff-839b-b1a70767812d' User entered '26 Apr 2021 13:40:44'	System	26 Apr 2021 18:40:48
	System	26 Apr 2021 18:40:48

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '26 Apr 2021 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '30 Apr 2021 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[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 (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2021-05-03T06:46:52-05:00', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '9b70d9cd-ddd1-4fb6-808c-f0d8a43bf58d'	System	03 May 2021 11:47:07
User entered 'No (N)'	System	03 May 2021 11:47:07

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

Have you been exposed to someone with 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 (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2021-05-03T06:46:56-05:00', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '9b70d9cd-ddd1-4fb6-808c-f0d8a43bf58d'	System	03 May 2021 11:47:07
User entered 'No (N)'	System	03 May 2021 11:47:07

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2021-05-03T06:47:02-05:00', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '9b70d9cd-ddd1-4fb6-808c-f0d8a43bf58d'	System	03 May 2021 11:47:07
User entered '03 May 2021 06:47:02'	System	03 May 2021 11:47:07

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '03 May 2021 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '07 May 2021 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '10 May 2021 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '14 May 2021 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '17 May 2021 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '21 May 2021 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '24 May 2021 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '28 May 2021 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '31 May 2021 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '04 Jun 2021 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '07 Jun 2021 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '11 Jun 2021 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '14 Jun 2021 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '18 Jun 2021 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '21 Jun 2021 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '25 Jun 2021 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '28 Jun 2021 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '02 Jul 2021 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '05 Jul 2021 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '09 Jul 2021 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '12 Jul 2021 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '16 Jul 2021 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '19 Jul 2021 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '23 Jul 2021 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '26 Jul 2021 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '30 Jul 2021 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '02 Aug 2021 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '06 Aug 2021 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '09 Aug 2021 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '13 Aug 2021 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '16 Aug 2021 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '20 Aug 2021 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '23 Aug 2021 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '27 Aug 2021 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '30 Aug 2021 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '03 Sep 2021 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '06 Sep 2021 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '10 Sep 2021 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '13 Sep 2021 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '17 Sep 2021 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '20 Sep 2021 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '24 Sep 2021 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '27 Sep 2021 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '01 Oct 2021 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '04 Oct 2021 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '08 Oct 2021 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '11 Oct 2021 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '15 Oct 2021 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '18 Oct 2021 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '22 Oct 2021 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '25 Oct 2021 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '29 Oct 2021 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '01 Nov 2021 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '05 Nov 2021 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '08 Nov 2021 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '12 Nov 2021 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '15 Nov 2021 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '19 Nov 2021 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '22 Nov 2021 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '26 Nov 2021 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '29 Nov 2021 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '03 Dec 2021 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '06 Dec 2021 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '10 Dec 2021 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '13 Dec 2021 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '17 Dec 2021 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '20 Dec 2021 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '24 Dec 2021 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '27 Dec 2021 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '31 Dec 2021 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '03 Jan 2022 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '07 Jan 2022 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '10 Jan 2022 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '14 Jan 2022 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '17 Jan 2022 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '21 Jan 2022 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '24 Jan 2022 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '28 Jan 2022 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '31 Jan 2022 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '04 Feb 2022 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '07 Feb 2022 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '11 Feb 2022 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '14 Feb 2022 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '18 Feb 2022 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '21 Feb 2022 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '25 Feb 2022 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '28 Feb 2022 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '04 Mar 2022 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '07 Mar 2022 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '11 Mar 2022 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '14 Mar 2022 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '18 Mar 2022 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '21 Mar 2022 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '25 Mar 2022 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '28 Mar 2022 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '01 Apr 2022 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '04 Apr 2022 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '08 Apr 2022 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '11 Apr 2022 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '15 Apr 2022 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '18 Apr 2022 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '22 Apr 2022 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '25 Apr 2022 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '29 Apr 2022 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '02 May 2022 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '06 May 2022 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '09 May 2022 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '13 May 2022 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '16 May 2022 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '20 May 2022 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '23 May 2022 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '27 May 2022 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '30 May 2022 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '03 Jun 2022 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '06 Jun 2022 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '10 Jun 2022 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '13 Jun 2022 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '17 Jun 2022 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '20 Jun 2022 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '24 Jun 2022 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '27 Jun 2022 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '01 Jul 2022 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '04 Jul 2022 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '08 Jul 2022 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '11 Jul 2022 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '15 Jul 2022 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '18 Jul 2022 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '22 Jul 2022 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '25 Jul 2022 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '29 Jul 2022 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '01 Aug 2022 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '05 Aug 2022 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '08 Aug 2022 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '12 Aug 2022 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '15 Aug 2022 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '19 Aug 2022 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '22 Aug 2022 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '26 Aug 2022 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '29 Aug 2022 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '02 Sep 2022 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '05 Sep 2022 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '09 Sep 2022 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '12 Sep 2022 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '16 Sep 2022 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '19 Sep 2022 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '23 Sep 2022 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '26 Sep 2022 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '30 Sep 2022 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '03 Oct 2022 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '07 Oct 2022 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '10 Oct 2022 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '14 Oct 2022 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '17 Oct 2022 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '21 Oct 2022 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '24 Oct 2022 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '28 Oct 2022 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '31 Oct 2022 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '04 Nov 2022 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '07 Nov 2022 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '11 Nov 2022 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '14 Nov 2022 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '18 Nov 2022 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:04:12

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)	25 Apr 2021 19:18:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2021-03-02T11:18:41-06:00', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '2fb2b751-519f-4975-b84c-c0e83eac66f7'	System	02 Mar 2021 17:21:58
User entered 'Yes (Y)'	System	02 Mar 2021 17:21:58

US3322329

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:04:12

Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:18:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2021-03-02T11:18:57-06:00', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '2fb2b751-519f-4975-b84c-c0e83eac66f7'	System	02 Mar 2021 17:21:58
User entered 'No (N)'	System	02 Mar 2021 17:21:58

US3322329

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:04:12

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:18:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2021-03-02T11:19:04-06:00', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '2fb2b751-519f-4975-b84c-c0e83eac66f7'	System	02 Mar 2021 17:21:58
User entered '02 Mar 2021 17:19:04'	System	02 Mar 2021 17:21:58

US3322329

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:04:12

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
DataPoint Verified.		03 Mar 2021 21:52:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'Yes (Y)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	07 Dec 2020 18:11:12

US3322329

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:04:12

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
DataPoint Verified.		03 Mar 2021 21:52:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered '07 Dec 2020'	(b) (4) Elisa Moralez (b) (4) (b) (4)	07 Dec 2020 18:11:12

US3322329

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:04:12

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
Query 'Please confirm answer with source.' canceled (Site from CRA).		05 Mar 2021 18:37:53
DataPoint Verified.		03 Mar 2021 21:55:51
User opened query 'Please confirm answer with source.' (Site from CRA).		03 Mar 2021 21:55:49
DataPoint Un-verified.		03 Mar 2021 21:55:20
DataPoint Verified.		03 Mar 2021 21:52:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	07 Dec 2020 18:11:12

US3322329

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:04:12

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
DataPoint Verified.		03 Mar 2021 21:52:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered empty.	(b) (4) Elisa Moralez (b) (4) (b) (4)	07 Dec 2020 18:11:12

US3322329

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:04:12

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
DataPoint Verified.		03 Mar 2021 21:55:55
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'Yes (Y)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	07 Dec 2020 18:11:04

US3322329

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:04:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:11:51
User entered 'I'	System	07 Dec 2020 18:11:04

US3322329

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:04:12

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:38:51
DataPoint Verified.		03 Mar 2021 21:57:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'Yes (Y)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	13 Jan 2021 18:51:06

US3322329

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:04:12

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:38:51
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:08:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 03:06:03
User closed query 'Per source date of safety call day 119 is 12Jan21. Please confirm with source and update accordingly.' (Site from CRA).		23 Mar 2021 03:05:51
Query 'Per source date of safety call day 119 is 12Jan21. Please confirm with source and update accordingly.' answered with 'that is correct, entry error, thank you' (Site from CRA).	Elisa Moralez (b) (4) (b) (4)	09 Mar 2021 21:59:13
DataPoint Un-verified.	Elisa Moralez (b) (4) (b) (4)	09 Mar 2021 21:59:04
Signature has been broken.	Elisa Moralez (b) (4) (b) (4)	09 Mar 2021 21:59:04
User entered '12 Jan 2021' reason for change: Data Entry Error	Elisa Moralez (b) (4) (b) (4)	09 Mar 2021 21:59:04
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 21:57:28
User opened query 'Per source date of safety call day 119 is 12Jan21. Please confirm with source and update accordingly.' (Site from CRA).		03 Mar 2021 21:57:17
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:58:34
User entered '13 Jan 2021'	Elisa Moralez (b) (4) (b) (4)	13 Jan 2021 18:51:06

US3322329

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:04:12

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:38:51
DataPoint Verified.		03 Mar 2021 21:57:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	13 Jan 2021 18:51:06

US3322329

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:04:12

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:38:51
DataPoint Verified.		03 Mar 2021 21:57:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered empty.	(b) (4) Elisa Moralez (b) (4) (b) (4)	13 Jan 2021 18:51:06

US3322329

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:04:12

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:38:51
DataPoint Verified.		03 Mar 2021 21:57:34
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'Yes (Y)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	13 Jan 2021 18:50:58

US3322329

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:04:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:38:51
User entered 'I'	System	13 Jan 2021 18:50:58

US3322329

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:04:12

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:38:51
DataPoint Verified.		03 Mar 2021 21:58:00
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'Yes (Y)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	20 Feb 2021 20:27:08

US3322329

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:04:12

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:38:51
DataPoint Verified.		03 Mar 2021 21:58:00
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered '09 Feb 2021'	(b) (4) Elisa Moralez (b) (4) (b) (4)	20 Feb 2021 20:27:08

US3322329

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:04:12

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:38:51
DataPoint Verified.		03 Mar 2021 21:58:00
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	20 Feb 2021 20:27:08

US3322329

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:04:12

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:38:51
DataPoint Verified.		03 Mar 2021 21:58:00
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered empty.	(b) (4) Elisa Moralez (b) (4) (b) (4)	20 Feb 2021 20:27:08

US3322329

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:04:12

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:38:51
DataPoint Verified.		03 Mar 2021 21:58:03
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'Yes (Y)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	20 Feb 2021 20:27:13

US3322329

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:04:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:38:51
User entered 'I'	System	20 Feb 2021 20:27:13

US3322329

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:04:12

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:28:19
DataPoint Verified.		15 Apr 2021 15:06:54
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:08:27
User entered 'Yes (Y)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	16 Mar 2021 19:31:23

US3322329

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:04:12

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:28:19
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:19:15
User closed query 'Per source, date of visit or contact attempt states 12Mar2021. Please confirm if this was entered incorrectly in source or EDC and update as needed. ' (Site from CRA).		20 Apr 2021 17:19:13
Signature has been broken.	Elisa Moralez (b) (4)	15 Apr 2021 15:57:30
User entered '12 Mar 2021' reason for change: Data Entry Error	(b) (4) Elisa Moralez (b) (4)	15 Apr 2021 15:57:30
Query 'Per source, date of visit or contact attempt states 12Mar2021. Please confirm if this was entered incorrectly in source or EDC and update as needed. ' answered with 'date is correct as 12mar, thank you' (Site from CRA).	(b) (4) Elisa Moralez (b) (4)	15 Apr 2021 15:57:25
User opened query 'Per source, date of visit or contact attempt states 12Mar2021. Please confirm if this was entered incorrectly in source or EDC and update as needed. ' (Site from CRA).	(b) (4), (b) (6)	15 Apr 2021 15:03:23
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:08:27
User entered '15 Mar 2021'	(b) (4) Elisa Moralez (b) (4) (b) (4)	16 Mar 2021 19:31:23

US3322329

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:04:12

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:28:19
DataPoint Verified.		15 Apr 2021 15:06:52
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:08:27
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	16 Mar 2021 19:31:23

US3322329

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:04:12

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:28:19
DataPoint Verified.		15 Apr 2021 15:06:56
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:08:27
User entered empty.	(b) (4) Elisa Moralez (b) (4) (b) (4)	16 Mar 2021 19:31:23

US3322329

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:04:12

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:28:19
DataPoint Verified.		15 Apr 2021 15:10:25
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:08:27
User entered 'Yes (Y)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	16 Mar 2021 19:31:10

US3322329

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:04:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:28:19
User entered 'I'	System	16 Mar 2021 19:31:10

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:04:12

[Date of Contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:56:21
User entered '05 Apr 2021'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:47:27

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:04:12

[Time of Contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 21:27:40
User entered '11:43' reason for change: Data Entry Error	Elisa Moralez (b) (4) (b) (4)	20 Apr 2021 17:20:59
DataPoint Un-verified.	(b) (4), (b) (6)	20 Apr 2021 16:56:28
DataPoint Verified.		20 Apr 2021 16:56:21
User entered '16:34'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:47:27

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:04:12

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
User entered '05 Apr 2021 11:43'	System	20 Apr 2021 17:20:59
User entered '05 Apr 2021 16:34'	System	12 Apr 2021 18:47:27

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:04:12

[Type of Contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
User closed query 'Thank you, please review time of contact. Per your comment and source call was made at 11:43. Thank you.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	20 Apr 2021 21:27:53
Query 'Thank you, please review time of contact. Per your comment and source call was made at 11:43. Thank you.' answered with 'updated' (Site from CRA).	Elisa Moralez (b) (4) (b) (4)	20 Apr 2021 17:21:03
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:56:21
User opened query 'Thank you, please review time of contact. Per your comment and source call was made at 11:43. Thank you.' (Site from CRA).		20 Apr 2021 16:56:07
User closed query 'Source progress notes state "Safety alert received via e dairy day 208, Voice message left , contact not established.". eDiary in source does not indicate whether an illness visit was required. Please confirm where in source this safety call took place and provide to CRA for verification. ' (Site from CRA).		20 Apr 2021 16:56:07
Query 'Source progress notes state "Safety alert received via e dairy day 208, Voice message left , contact not established.". eDiary in source does not indicate whether an illness visit was required. Please confirm where in source this safety call took place and provide to CRA for verification. ' answered with 'per source entry for record 1, contact was made on 5APR2021 at 11:43, surveillance for COVID-19 was entered at 16:08, patient did come in for illness visit, so this is deduced to be the time contact was made' (Site from CRA).	Elisa Moralez (b) (4) (b) (4)	15 Apr 2021 15:56:35
User opened query 'Source progress notes state "Safety alert received via e dairy day 208, Voice message left , contact not established.". eDiary in source does not indicate whether an illness visit was required. Please confirm where in source this safety call took place and provide to CRA for verification. ' (Site from CRA).	(b) (4), (b) (6)	15 Apr 2021 15:22:44
User entered 'Safety Call (Safety Call)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:47:27

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:04:12

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:56:21
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:47:27

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:04:12

[Symptom Day](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
User entered 'Day 1 (Day 1)'	(b) (4) Elisa Morales (b) (4)	12 Apr 2021 18:56:33
	(b) (4)	

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Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:04:12

[Date](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:14:21
User entered '29 Mar 2021'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

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Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:04:12

[Assessment Not Done](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:14:21
User entered '0'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

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Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:04:12

[O2 Saturation](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:14:21
User entered missing code ND - Not Done.	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

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Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:04:12

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	12 Apr 2021 18:56:33

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Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:04:12

[Temperature](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:14:21
User entered '100.4' F	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:04:12

[Chills](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:14:21
User entered 'Mild (Mild)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:04:12

[Cough](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:14:21
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:04:12

[Shortness of Breath](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:14:21
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:04:12

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:14:21
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:04:12

[Fatigue](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:14:21
User entered 'Mild (Mild)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:04:12

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:14:21
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:04:12

[Body Aches](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:14:21
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:04:12

[Headache](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:14:21
User entered 'Mild (Mild)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:04:12

[New Loss of Taste](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:14:21
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:04:12

[New Loss of Smell](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:14:21
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:04:12

[Nasal Congestion](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:14:21
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

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Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:04:12

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:14:21
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

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Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:04:12

[Nausea](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:14:21
User entered 'Mild (Mild)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:04:12

[Vomiting](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:14:21
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

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Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:04:12

[Diarrhea](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:14:21
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:04:12

[Sore Throat](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:14:21
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:04:12

[Symptom Day](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
	(b) (4)	
User entered 'Day 2 (Day 2)'	Elisa Morales (b) (4)	12 Apr 2021 18:56:33
	(b) (4)	

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Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:04:12

[Date](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:14:22
User entered '30 Mar 2021'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

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Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:04:12

[Assessment Not Done](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Apr 2021 17:14:22
User entered '0'	Elisa Moralez (b) (4)	12 Apr 2021 18:56:33
	(b) (4)	

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Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:04:12

[O2 Saturation](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:14:22
User entered missing code ND - Not Done.	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

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Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:04:12

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	12 Apr 2021 18:56:33

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Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:04:12

[Temperature](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:14:22
User entered missing code ND - Not Done.	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

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Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:04:12

[Chills](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:14:22
User entered 'Mild (Mild)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:04:12

[Cough](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:14:22
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:04:12

[Shortness of Breath](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:14:22
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:04:12

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:14:22
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:04:12

[Fatigue](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:14:22
User entered 'Mild (Mild)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:04:12

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:14:22
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:04:12

[Body Aches](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:14:22
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:04:12

[Headache](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:14:22
User entered 'Mild (Mild)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:04:12

[New Loss of Taste](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:14:22
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:04:12

[New Loss of Smell](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:14:22
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

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Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:04:12

[Nasal Congestion](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:14:22
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

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Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:04:12

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:14:22
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:04:12

[Nausea](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:14:22
User entered 'Mild (Mild)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:04:12

[Vomiting](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:14:22
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:04:12

[Diarrhea](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:14:22
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:04:12

[Sore Throat](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:14:22
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:04:12

[Symptom Day](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
User entered 'Day 3 (Day 3)'	(b) (4) Elisa Morales (b) (4)	12 Apr 2021 18:56:33
	(b) (4)	

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Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:04:12

[Date](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:15:26
User entered '31 Mar 2021'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

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Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:04:12

[Assessment Not Done](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:15:26
User entered '0'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:04:12

[O2 Saturation](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:15:26
User entered missing code ND - Not Done.	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

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Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:04:12

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:04:12

[Temperature](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:15:26
User entered missing code ND - Not Done.	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:04:12

[Chills](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:15:26
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:04:12

[Cough](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:15:26
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:04:12

[Shortness of Breath](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:15:26
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:04:12

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:15:26
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:04:12

[Fatigue](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:15:26
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:04:12

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:15:26
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:04:12

[Body Aches](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:15:26
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:04:12

[Headache](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:15:26
User entered 'Mild (Mild)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:04:12

[New Loss of Taste](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:15:26
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:04:12

[New Loss of Smell](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:15:26
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:04:12

[Nasal Congestion](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:15:26
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:04:12

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:15:26
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:04:12

[Nausea](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:15:26
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:04:12

[Vomiting](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:15:26
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:04:12

[Diarrhea](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:15:26
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:04:12

[Sore Throat](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:15:26
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:04:12

[Symptom Day](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
	(b) (4)	
User entered 'Day 4 (Day 4)'	Elisa Morales (b) (4)	12 Apr 2021 18:56:33
	(b) (4)	

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:04:12

[Date](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:15:30
User entered '01 Apr 2021'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:04:12

[Assessment Not Done](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:15:30
User entered '0'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:04:12

[O2 Saturation](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:15:30
User entered missing code ND - Not Done.	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:04:12

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:04:12

[Temperature](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:15:30
User entered missing code ND - Not Done.	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:04:12

[Chills](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:15:30
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:04:12

[Cough](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:15:30
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:04:12

[Shortness of Breath](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:15:30
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:04:12

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:15:30
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:04:12

[Fatigue](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:15:30
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:04:12

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:15:30
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:04:12

[Body Aches](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:15:30
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:04:12

[Headache](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:15:30
User entered 'Mild (Mild)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:04:12

[New Loss of Taste](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:15:30
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:04:12

[New Loss of Smell](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:15:30
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:04:12

[Nasal Congestion](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:15:30
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:04:12

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:15:30
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:04:12

[Nausea](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:15:30
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:04:12

[Vomiting](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:15:30
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:04:12

[Diarrhea](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:15:30
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:04:12

[Sore Throat](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:15:30
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:04:12

[Symptom Day](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
	(b) (4)	
User entered 'Day 5 (Day 5)'	Elisa Morales (b) (4)	12 Apr 2021 18:56:33
	(b) (4)	

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Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:04:12

[Date](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:15:36
User entered '02 Apr 2021'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:04:12

[Assessment Not Done](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:15:36
User entered '0'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:04:12

[O2 Saturation](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:15:36
User entered missing code ND - Not Done.	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:04:12

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:04:12

[Temperature](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:15:36
User entered missing code ND - Not Done.	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:04:12

[Chills](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:15:36
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:04:12

[Cough](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:15:36
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:04:12

[Shortness of Breath](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:15:36
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:04:12

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:15:36
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:04:12

[Fatigue](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:15:36
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:04:12

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:15:36
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:04:12

[Body Aches](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:15:36
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:04:12

[Headache](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:15:36
User entered 'Mild (Mild)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:04:12

[New Loss of Taste](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:15:36
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:04:12

[New Loss of Smell](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:15:36
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:04:12

[Nasal Congestion](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:15:36
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:04:12

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:15:36
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:04:12

[Nausea](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:15:36
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:04:12

[Vomiting](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:15:36
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:04:12

[Diarrhea](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:15:36
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:04:12

[Sore Throat](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:15:36
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:04:12

[Symptom Day](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
User entered 'Day 6 (Day 6)'	(b) (4) Elisa Morales (b) (4)	12 Apr 2021 18:56:33
	(b) (4)	

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:04:12

[Date](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:18:28
DataPoint Un-verified.		20 Apr 2021 17:16:13
DataPoint Verified.		20 Apr 2021 17:15:41
User entered '03 Apr 2021'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:04:12

[Assessment Not Done](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:18:28
DataPoint Un-verified.		20 Apr 2021 17:16:13
DataPoint Verified.		20 Apr 2021 17:15:41
User entered '0'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:04:12

[O2 Saturation](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:18:28
DataPoint Un-verified.		20 Apr 2021 17:16:13
DataPoint Verified.		20 Apr 2021 17:15:41
User entered missing code ND - Not Done.	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:04:12

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:04:12

[Temperature](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:18:28
DataPoint Un-verified.		20 Apr 2021 17:16:13
DataPoint Verified.		20 Apr 2021 17:15:41
User entered missing code ND - Not Done.	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:04:12

[Chills](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:18:28
DataPoint Un-verified.		20 Apr 2021 17:16:13
DataPoint Verified.		20 Apr 2021 17:15:41
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:04:12

[Cough](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:18:28
DataPoint Un-verified.		20 Apr 2021 17:16:13
DataPoint Verified.		20 Apr 2021 17:15:41
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:04:12

[Shortness of Breath](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:18:28
DataPoint Un-verified.		20 Apr 2021 17:16:13
DataPoint Verified.		20 Apr 2021 17:15:41
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:04:12

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:18:28
DataPoint Un-verified.		20 Apr 2021 17:16:13
DataPoint Verified.		20 Apr 2021 17:15:41
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:04:12

[Fatigue](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:18:28
DataPoint Un-verified.		20 Apr 2021 17:16:13
DataPoint Verified.		20 Apr 2021 17:15:41
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:04:12

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:18:28
DataPoint Un-verified.		20 Apr 2021 17:16:13
DataPoint Verified.		20 Apr 2021 17:15:41
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:04:12

[Body Aches](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:18:28
DataPoint Un-verified.		20 Apr 2021 17:16:13
DataPoint Verified.		20 Apr 2021 17:15:41
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:04:12

[Headache](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:18:28
DataPoint Un-verified.		20 Apr 2021 17:16:13
DataPoint Verified.		20 Apr 2021 17:15:41
User entered 'Mild (Mild)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:04:12

[New Loss of Taste](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:18:28
DataPoint Un-verified.		20 Apr 2021 17:16:13
DataPoint Verified.		20 Apr 2021 17:15:41
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:04:12

[New Loss of Smell](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:18:28
DataPoint Un-verified.		20 Apr 2021 17:16:13
DataPoint Verified.		20 Apr 2021 17:15:41
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:04:12

[Nasal Congestion](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:18:28
DataPoint Un-verified.		20 Apr 2021 17:16:13
DataPoint Verified.		20 Apr 2021 17:15:41
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:04:12

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4)	20 Apr 2021 17:18:28
DataPoint Un-verified.	(b) (4), (b) (6)	20 Apr 2021 17:16:13
DataPoint Verified.		20 Apr 2021 17:15:41
User entered 'None (None)'	Elisa Moralez (b) (4)	12 Apr 2021 18:56:33
	(b) (4)	

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Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:04:12

[Nausea](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:18:28
DataPoint Un-verified.		20 Apr 2021 17:16:13
DataPoint Verified.		20 Apr 2021 17:15:41
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:04:12

[Vomiting](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:18:28
DataPoint Un-verified.		20 Apr 2021 17:16:13
DataPoint Verified.		20 Apr 2021 17:15:41
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:04:12

[Diarrhea](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4)	20 Apr 2021 17:18:28
DataPoint Un-verified.	(b) (4), (b) (6)	20 Apr 2021 17:16:13
DataPoint Verified.		20 Apr 2021 17:15:41
User entered 'None (None)'	Elisa Moralez (b) (4)	12 Apr 2021 18:56:33
	(b) (4)	

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:04:12

[Sore Throat](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:18:28
DataPoint Un-verified.		20 Apr 2021 17:16:13
DataPoint Verified.		20 Apr 2021 17:15:41
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:04:12

[Symptom Day](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
	(b) (4)	
User entered 'Day 7 (Day 7)'	Elisa Morales (b) (4)	12 Apr 2021 18:56:33
	(b) (4)	

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Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:04:12

[Date](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:16:10
User entered '04 Apr 2021'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:04:12

[Assessment Not Done](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:16:10
User entered '0'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:04:12

[O2 Saturation](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:16:10
User entered missing code ND - Not Done.	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:04:12

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	12 Apr 2021 18:56:33

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Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:04:12

[Temperature](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:16:10
User entered missing code ND - Not Done.	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:04:12

[Chills](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:16:10
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:04:12

[Cough](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:16:10
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:04:12

[Shortness of Breath](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:16:10
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:04:12

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:16:10
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:04:12

[Fatigue](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Apr 2021 17:16:10
User entered 'None (None)'	Elisa Moralez (b) (4)	12 Apr 2021 18:56:33
	(b) (4)	

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:04:12

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:16:10
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:04:12

[Body Aches](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:16:10
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:04:12

[Headache](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:16:10
User entered 'Mild (Mild)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:04:12

[New Loss of Taste](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:16:10
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:04:12

[New Loss of Smell](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:16:10
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:04:12

[Nasal Congestion](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:16:10
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:04:12

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:16:10
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:04:12

[Nausea](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:16:10
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:04:12

[Vomiting](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:16:10
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:04:12

[Diarrhea](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:16:10
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:04:12

[Sore Throat](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:16:10
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:04:12

[Symptom Day](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
	(b) (4)	
User entered 'Day 8 (Day 8)'	Elisa Morales (b) (4)	12 Apr 2021 18:56:33
	(b) (4)	

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:04:12

[Date](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:16:54
User entered '05 Apr 2021'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:04:12

[Assessment Not Done](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:16:54
User entered '0'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:04:12

[O2 Saturation](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:16:54
User entered missing code ND - Not Done.	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:04:12

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:04:12

[Temperature](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:16:54
User entered missing code ND - Not Done.	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:04:12

[Chills](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:16:54
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:04:12

[Cough](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:16:54
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:04:12

[Shortness of Breath](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:16:54
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:04:12

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:16:54
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:04:12

[Fatigue](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:16:54
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:04:12

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:16:54
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:04:12

[Body Aches](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:16:54
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:04:12

[Headache](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:16:54
User entered 'Mild (Mild)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:04:12

[New Loss of Taste](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:16:54
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:04:12

[New Loss of Smell](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:16:54
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:04:12

[Nasal Congestion](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:16:54
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:04:12

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:16:54
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:04:12

[Nausea](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:16:54
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:04:12

[Vomiting](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:16:54
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:04:12

[Diarrhea](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:16:54
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:04:12

[Sore Throat](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:16:54
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:04:12

[Symptom Day](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
	(b) (4)	
User entered 'Day 9 (Day 9)'	Elisa Morales (b) (4)	12 Apr 2021 18:56:33
	(b) (4)	

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:04:12

[Date](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:42:26
User entered '06 Apr 2021'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:04:12

[Assessment Not Done](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:42:28
User entered '0'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:04:12

[O2 Saturation](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:42:29
User entered '99'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:04:12

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:04:12

[Temperature](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:42:31
User entered '96.4' F	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:04:12

[Chills](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:16:58
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:04:12

[Cough](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:16:58
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:04:12

[Shortness of Breath](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:16:58
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:04:12

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:16:58
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:04:12

[Fatigue](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:16:58
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:04:12

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:16:58
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:04:12

[Body Aches](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:16:58
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:04:12

[Headache](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:16:58
User entered 'Mild (Mild)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:04:12

[New Loss of Taste](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:16:58
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:04:12

[New Loss of Smell](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:16:58
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:04:12

[Nasal Congestion](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:16:58
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:04:12

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:16:58
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:04:12

[Nausea](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:16:58
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:04:12

[Vomiting](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:16:58
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:04:12

[Diarrhea](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:16:58
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:04:12

[Sore Throat](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:16:58
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:04:12

[Symptom Day](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
	(b) (4)	
User entered 'Day 10 (Day 10)'	Elisa Morales (b) (4)	12 Apr 2021 18:56:33
	(b) (4)	

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:04:12

[Date](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:44:00
User entered '07 Apr 2021'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:04:12

[Assessment Not Done](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:44:02
User entered '0'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:04:12

[O2 Saturation](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:44:04
User entered '98'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:04:12

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:04:12

[Temperature](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:44:05
User entered '97.8' F	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:04:12

[Chills](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:44:08
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:04:12

[Cough](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:44:10
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:04:12

[Shortness of Breath](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:44:12
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:04:12

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:44:15
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:04:12

[Fatigue](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:44:17
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:04:12

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:44:18
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:04:12

[Body Aches](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:44:20
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:04:12

[Headache](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:44:21
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:04:12

[New Loss of Taste](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:44:23
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:04:12

[New Loss of Smell](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:44:24
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:04:12

[Nasal Congestion](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:44:26
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:04:12

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:44:28
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:04:12

[Nausea](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:44:29
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:04:12

[Vomiting](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:44:31
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:04:12

[Diarrhea](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:44:32
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:04:12

[Sore Throat](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:44:33
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:04:12

[Symptom Day](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
User entered 'Day 11 (Day 11)'	(b) (4) Elisa Morales (b) (4)	12 Apr 2021 18:56:33
	(b) (4)	

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:04:12

[Date](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:44:59
User entered '08 Apr 2021'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:04:12

[Assessment Not Done](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:45:01
User entered '0'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:04:12

[O2 Saturation](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:45:02
User entered '98'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:04:12

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:04:12

[Temperature](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:45:04
User entered '98.1' F	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:04:12

[Chills](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:45:05
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:04:12

[Cough](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:45:07
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:04:12

[Shortness of Breath](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:45:08
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:04:12

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:45:10
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:04:12

[Fatigue](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:45:54
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:04:12

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:45:56
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:04:12

[Body Aches](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:45:58
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:04:12

[Headache](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:46:00
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:04:12

[New Loss of Taste](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:46:02
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:04:12

[New Loss of Smell](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:46:03
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:04:12

[Nasal Congestion](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:46:05
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:04:12

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:46:06
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:04:12

[Nausea](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:46:08
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:04:12

[Vomiting](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:46:10
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:04:12

[Diarrhea](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:46:12
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:04:12

[Sore Throat](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:46:14
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:04:12

[Symptom Day](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
	(b) (4)	
User entered 'Day 12 (Day 12)'	Elisa Morales (b) (4)	12 Apr 2021 18:56:33
	(b) (4)	

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:04:12

[Date](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:46:39
User entered '09 Apr 2021'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:04:12

[Assessment Not Done](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:46:41
User entered '0'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:04:12

[O2 Saturation](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:46:42
User entered '97'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:04:12

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:04:12

[Temperature](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:47:00
User entered '98.1' F	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:04:12

[Chills](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:47:01
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:04:12

[Cough](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:47:12
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:04:12

[Shortness of Breath](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:47:13
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:04:12

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:47:15
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:04:12

[Fatigue](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:48:35
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:04:12

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:48:37
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:04:12

[Body Aches](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:48:38
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:04:12

[Headache](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:48:40
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:04:12

[New Loss of Taste](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:48:41
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:04:12

[New Loss of Smell](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:48:43
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:04:12

[Nasal Congestion](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:48:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:04:12

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:48:46
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:04:12

[Nausea](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:49:02
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:04:12

[Vomiting](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:49:04
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:04:12

[Diarrhea](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:49:06
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:04:12

[Sore Throat](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:49:08
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:04:12

[Symptom Day](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
User entered 'Day 13 (Day 13)'	(b) (4) Elisa Morales (b) (4)	12 Apr 2021 18:56:33
	(b) (4)	

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Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:04:12

[Date](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:51:56
User entered '10 Apr 2021'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:04:12

[Assessment Not Done](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:51:58
User entered '0'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:04:12

[O2 Saturation](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:52:05
User entered '99'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:04:12

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:04:12

[Temperature](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:52:07
User entered '97.8' F	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:04:12

[Chills](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:52:22
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:04:12

[Cough](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:52:23
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:04:12

[Shortness of Breath](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:52:25
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:04:12

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:52:26
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:04:12

[Fatigue](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:52:28
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:04:12

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:52:31
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:04:12

[Body Aches](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:52:32
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:04:12

[Headache](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:52:34
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:04:12

[New Loss of Taste](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:52:36
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:04:12

[New Loss of Smell](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:52:20
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:04:12

[Nasal Congestion](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:52:18
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:04:12

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:52:17
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

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Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:04:12

[Nausea](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:52:14
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:04:12

[Vomiting](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:52:13
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:04:12

[Diarrhea](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:52:12
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:04:12

[Sore Throat](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:52:10
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:04:12

[Symptom Day](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
User entered 'Day 14 (Day 14)'	(b) (4) Elisa Morales (b) (4)	12 Apr 2021 18:56:33
	(b) (4)	

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Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:04:12

[Date](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:55:06
User entered '11 Apr 2021'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:04:12

[Assessment Not Done](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:55:07
User entered '0'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:04:12

[O2 Saturation](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:55:09
User entered '98'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:04:12

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:04:12

[Temperature](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:55:10
User entered '97.8' F	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:04:12

[Chills](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:55:12
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:04:12

[Cough](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:55:14
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:04:12

[Shortness of Breath](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:55:15
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:04:12

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:55:17
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:04:12

[Fatigue](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:55:18
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:04:12

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:56:12
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:04:12

[Body Aches](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:56:14
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:04:12

[Headache](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:56:15
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:04:12

[New Loss of Taste](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:56:17
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:04:12

[New Loss of Smell](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:56:19
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:04:12

[Nasal Congestion](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:56:29
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:04:12

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:56:30
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:04:12

[Nausea](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:56:32
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:04:12

[Vomiting](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:56:34
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:04:12

[Diarrhea](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:56:35
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:04:12

[Sore Throat](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:56:37
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:33

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:04:12

[Date of Visit](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:35:22
User entered '06 Apr 2021'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:48

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:04:12

Was the Subject Tested For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:35:22
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:48

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:04:12

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:35:22
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:48

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:04:12

[Date of Test](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:35:22
User entered '06 Apr 2021'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:48

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:04:12

[Type of Test Performed](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:35:22
User entered 'Nasal Swab (Nasal Swab)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:48

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:04:12

[Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:35:22
User entered empty.	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:48

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:04:12

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:35:22
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:48

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:04:12

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:35:22
User entered empty.	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:48

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:04:12

[CLIA Certified?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:35:22
User entered empty.	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:56:48

US3322329

Folder: Covid-19 Assessment 05 Apr 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:04:12

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	12 Apr 2021 18:56:48

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:04:12

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:52
DataPoint Verified.		03 Mar 2021 21:59:09
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered '13 Jan 2021'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:16:40

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:04:12

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:52
DataPoint Verified.		03 Mar 2021 21:59:09
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered '12:00'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:16:40

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:04:12

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:52
User entered '13 Jan 2021 12:00'	System	19 Jan 2021 16:16:40

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:04:12

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:52
DataPoint Verified.		03 Mar 2021 21:59:09
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'Safety Call (Safety Call)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:16:40

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Folder: Covid-19 Assessment 13 Jan 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:04:12

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:52
DataPoint Verified.		03 Mar 2021 21:59:09
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'Yes (Y)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:16:40

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:04:12

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'Day 1 (Day 1)'	Elisa Moralez (b) (4)	19 Jan 2021 16:24:51

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:04:12

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
DataPoint Verified.		03 Mar 2021 22:09:53
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered '11 Jan 2021'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:04:12

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
DataPoint Verified.		03 Mar 2021 22:09:53
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered '0'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:04:12

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
DataPoint Verified.		03 Mar 2021 22:09:53
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered missing code ND - Not Done.	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:24:51

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:04:12

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
User entered '%'	System	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:04:12

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
DataPoint Verified.		03 Mar 2021 22:09:53
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered missing code ND - Not Done.	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:04:12

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
DataPoint Verified.		03 Mar 2021 22:09:53
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:04:12

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
DataPoint Verified.		03 Mar 2021 22:09:53
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'Mild (Mild)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:04:12

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
DataPoint Verified.		03 Mar 2021 22:09:53
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:04:12

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
DataPoint Verified.		03 Mar 2021 22:09:53
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:04:12

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
DataPoint Verified.		03 Mar 2021 22:09:53
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:04:12

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
DataPoint Verified.		03 Mar 2021 22:09:53
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:04:12

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
DataPoint Verified.		03 Mar 2021 22:09:53
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:04:12

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
DataPoint Verified.		03 Mar 2021 22:09:53
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'Mild (Mild)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:04:12

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
DataPoint Verified.		03 Mar 2021 22:09:53
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:04:12

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
DataPoint Verified.		03 Mar 2021 22:09:53
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:04:12

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
DataPoint Verified.		03 Mar 2021 22:09:53
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:04:12

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
DataPoint Verified.		03 Mar 2021 22:09:53
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'Mild (Mild)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:24:51

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:04:12

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
DataPoint Verified.		03 Mar 2021 22:09:53
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:04:12

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
DataPoint Verified.		03 Mar 2021 22:09:53
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:04:12

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
DataPoint Verified.		03 Mar 2021 22:09:53
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:04:12

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
DataPoint Verified.		03 Mar 2021 22:09:53
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'Mild (Mild)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:04:12

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'Day 2 (Day 2)'	Elisa Moralez (b) (4)	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:04:12

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
DataPoint Verified.		03 Mar 2021 22:09:53
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered '12 Jan 2021'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:04:12

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
DataPoint Verified.		03 Mar 2021 22:09:53
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered '0'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:04:12

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
DataPoint Verified.		03 Mar 2021 22:09:53
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered missing code ND - Not Done.	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:24:51

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:04:12

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
User entered '%'	System	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:04:12

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
DataPoint Verified.		03 Mar 2021 22:09:53
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered missing code ND - Not Done.	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:04:12

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
DataPoint Verified.		03 Mar 2021 22:09:53
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:04:12

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
DataPoint Verified.		03 Mar 2021 22:09:53
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'Mild (Mild)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:04:12

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
DataPoint Verified.		03 Mar 2021 22:09:53
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:04:12

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
DataPoint Verified.		03 Mar 2021 22:09:53
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:04:12

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
DataPoint Verified.		03 Mar 2021 22:09:53
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:04:12

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
DataPoint Verified.		03 Mar 2021 22:09:53
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:04:12

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
DataPoint Verified.		03 Mar 2021 22:09:53
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:04:12

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
DataPoint Verified.		03 Mar 2021 22:09:53
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:04:12

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
DataPoint Verified.		03 Mar 2021 22:09:53
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:04:12

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
DataPoint Verified.		03 Mar 2021 22:09:53
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:04:12

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
DataPoint Verified.		03 Mar 2021 22:09:53
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:04:12

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
DataPoint Verified.		03 Mar 2021 22:09:53
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'Mild (Mild)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:04:12

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
DataPoint Verified.		03 Mar 2021 22:09:53
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:04:12

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
DataPoint Verified.		03 Mar 2021 22:09:53
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:04:12

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
DataPoint Verified.		03 Mar 2021 22:09:53
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:04:12

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
DataPoint Verified.		03 Mar 2021 22:09:53
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'Mild (Mild)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:04:12

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'Day 3 (Day 3)'	Elisa Moralez (b) (4)	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:04:12

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
DataPoint Verified.		03 Mar 2021 22:09:59
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered '13 Jan 2021'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:04:12

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
DataPoint Verified.		03 Mar 2021 22:09:59
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered '0'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:04:12

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
DataPoint Verified.		03 Mar 2021 22:09:59
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered missing code ND - Not Done.	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:04:12

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
User entered '%'	System	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:04:12

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
DataPoint Verified.		03 Mar 2021 22:09:59
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered '96.6' F	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:04:12

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
DataPoint Verified.		03 Mar 2021 22:09:59
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:04:12

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
DataPoint Verified.		03 Mar 2021 22:09:59
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'Mild (Mild)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:04:12

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
DataPoint Verified.		03 Mar 2021 22:09:59
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:04:12

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
DataPoint Verified.		03 Mar 2021 22:09:59
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:04:12

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
DataPoint Verified.		03 Mar 2021 22:09:59
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:04:12

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
DataPoint Verified.		03 Mar 2021 22:09:59
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:04:12

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
DataPoint Verified.		03 Mar 2021 22:09:59
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:04:12

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
DataPoint Verified.		03 Mar 2021 22:09:59
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:04:12

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
DataPoint Verified.		03 Mar 2021 22:09:59
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:04:12

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
DataPoint Verified.		03 Mar 2021 22:09:59
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:04:12

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
DataPoint Verified.		03 Mar 2021 22:09:59
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:04:12

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
DataPoint Verified.		03 Mar 2021 22:09:59
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'Mild (Mild)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:04:12

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
DataPoint Verified.		03 Mar 2021 22:09:59
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:04:12

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
DataPoint Verified.		03 Mar 2021 22:09:59
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:04:12

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
DataPoint Verified.		03 Mar 2021 22:09:59
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:04:12

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
DataPoint Verified.		03 Mar 2021 22:09:59
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'Mild (Mild)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:04:12

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'Day 4 (Day 4)'	Elisa Moralez (b) (4)	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:04:12

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
DataPoint Verified.		03 Mar 2021 22:14:12
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered '14 Jan 2021'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:04:12

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
DataPoint Verified.		03 Mar 2021 22:14:12
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered '0'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:04:12

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
DataPoint Verified.		03 Mar 2021 22:14:12
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered '98'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:04:12

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
User entered '%'	System	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:04:12

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
DataPoint Verified.		03 Mar 2021 22:14:12
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered '97.9' F	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:04:12

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
DataPoint Verified.		03 Mar 2021 22:14:12
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:04:12

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
DataPoint Verified.		03 Mar 2021 22:14:12
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:04:12

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
DataPoint Verified.		03 Mar 2021 22:14:12
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:04:12

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
DataPoint Verified.		03 Mar 2021 22:14:12
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:04:12

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
DataPoint Verified.		03 Mar 2021 22:14:12
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:04:12

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
DataPoint Verified.		03 Mar 2021 22:14:12
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:04:12

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
DataPoint Verified.		03 Mar 2021 22:14:12
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:04:12

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
DataPoint Verified.		03 Mar 2021 22:14:12
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:04:12

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
DataPoint Verified.		03 Mar 2021 22:14:12
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:04:12

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
DataPoint Verified.		03 Mar 2021 22:14:12
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:04:12

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
DataPoint Verified.		03 Mar 2021 22:14:12
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:04:12

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
DataPoint Verified.		03 Mar 2021 22:14:12
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'Mild (Mild)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:04:12

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
DataPoint Verified.		03 Mar 2021 22:14:12
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:04:12

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
DataPoint Verified.		03 Mar 2021 22:14:12
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:04:12

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
DataPoint Verified.		03 Mar 2021 22:14:12
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:04:12

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
DataPoint Verified.		03 Mar 2021 22:14:12
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:04:12

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'Day 5 (Day 5)'	Elisa Moralez (b) (4)	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:04:12

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
DataPoint Verified.		03 Mar 2021 22:14:14
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered '15 Jan 2021'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:04:12

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
DataPoint Verified.		03 Mar 2021 22:14:14
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered '0'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:04:12

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
DataPoint Verified.		03 Mar 2021 22:14:14
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered '100'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:04:12

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
User entered '%'	System	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:04:12

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
DataPoint Verified.		03 Mar 2021 22:14:14
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered '98.2' F	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:04:12

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
DataPoint Verified.		03 Mar 2021 22:14:14
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:04:12

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
DataPoint Verified.		03 Mar 2021 22:14:14
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:04:12

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
DataPoint Verified.		03 Mar 2021 22:14:14
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:04:12

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
DataPoint Verified.		03 Mar 2021 22:14:14
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:04:12

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
DataPoint Verified.		03 Mar 2021 22:14:14
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:04:12

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
DataPoint Verified.		03 Mar 2021 22:14:14
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:04:12

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
DataPoint Verified.		03 Mar 2021 22:14:14
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:04:12

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
DataPoint Verified.		03 Mar 2021 22:14:14
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:04:12

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
DataPoint Verified.		03 Mar 2021 22:14:14
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:04:12

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
DataPoint Verified.		03 Mar 2021 22:14:14
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:04:12

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
DataPoint Verified.		03 Mar 2021 22:14:14
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:04:12

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
DataPoint Verified.		03 Mar 2021 22:14:14
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'Mild (Mild)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:04:12

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
DataPoint Verified.		03 Mar 2021 22:14:14
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:04:12

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
DataPoint Verified.		03 Mar 2021 22:14:14
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:04:12

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
DataPoint Verified.		03 Mar 2021 22:14:14
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:04:12

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
DataPoint Verified.		03 Mar 2021 22:14:14
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:04:12

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'Day 6 (Day 6)'	Elisa Moralez (b) (4)	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:04:12

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
DataPoint Verified.		03 Mar 2021 22:14:15
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered '16 Jan 2021'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:04:12

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
DataPoint Verified.		03 Mar 2021 22:14:15
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered '0'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:04:12

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
DataPoint Verified.		03 Mar 2021 22:14:15
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered '100'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:04:12

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
User entered '%'	System	19 Jan 2021 16:24:51

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:04:12

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
DataPoint Verified.		03 Mar 2021 22:14:15
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered '98.1' F	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:04:12

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
DataPoint Verified.		03 Mar 2021 22:14:15
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:04:12

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
DataPoint Verified.		03 Mar 2021 22:14:15
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:04:12

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
DataPoint Verified.		03 Mar 2021 22:14:15
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:04:12

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
DataPoint Verified.		03 Mar 2021 22:14:15
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:04:12

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
DataPoint Verified.		03 Mar 2021 22:14:15
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:04:12

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
DataPoint Verified.		03 Mar 2021 22:14:15
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:04:12

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
DataPoint Verified.		03 Mar 2021 22:14:15
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:04:12

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
DataPoint Verified.		03 Mar 2021 22:14:15
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:04:12

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
DataPoint Verified.		03 Mar 2021 22:14:15
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:04:12

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
DataPoint Verified.		03 Mar 2021 22:14:15
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:04:12

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
DataPoint Verified.		03 Mar 2021 22:14:15
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:04:12

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
DataPoint Verified.		03 Mar 2021 22:14:15
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:24:51

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:04:12

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
DataPoint Verified.		03 Mar 2021 22:14:15
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:04:12

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
DataPoint Verified.		03 Mar 2021 22:14:15
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:04:12

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
DataPoint Verified.		03 Mar 2021 22:14:15
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:04:12

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
DataPoint Verified.		03 Mar 2021 22:14:15
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:04:12

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'Day 7 (Day 7)'	Elisa Moralez (b) (4)	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:04:12

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
DataPoint Verified.		03 Mar 2021 22:14:19
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered '17 Jan 2021'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:04:12

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
DataPoint Verified.		03 Mar 2021 22:14:19
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered '0'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:04:12

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
DataPoint Verified.		03 Mar 2021 22:14:19
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered '99'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:04:12

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
User entered '%'	System	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:04:12

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
DataPoint Verified.		03 Mar 2021 22:14:19
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered '97' F	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:04:12

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
DataPoint Verified.		03 Mar 2021 22:14:19
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:04:12

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
DataPoint Verified.		03 Mar 2021 22:14:19
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:04:12

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
DataPoint Verified.		03 Mar 2021 22:14:19
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:04:12

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
DataPoint Verified.		03 Mar 2021 22:14:19
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:04:12

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
DataPoint Verified.		03 Mar 2021 22:14:19
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:04:12

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
DataPoint Verified.		03 Mar 2021 22:14:19
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:04:12

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
DataPoint Verified.		03 Mar 2021 22:14:19
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:04:12

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
DataPoint Verified.		03 Mar 2021 22:14:19
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:04:12

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
DataPoint Verified.		03 Mar 2021 22:14:19
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:04:12

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
DataPoint Verified.		03 Mar 2021 22:14:19
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:04:12

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
DataPoint Verified.		03 Mar 2021 22:14:19
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:04:12

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
DataPoint Verified.		03 Mar 2021 22:14:19
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:04:12

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
DataPoint Verified.		03 Mar 2021 22:14:19
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:04:12

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
DataPoint Verified.		03 Mar 2021 22:14:19
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:04:12

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
DataPoint Verified.		03 Mar 2021 22:14:19
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:04:12

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
DataPoint Verified.		03 Mar 2021 22:14:19
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:04:12

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'Day 8 (Day 8)'	Elisa Moralez (b) (4)	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:04:12

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
DataPoint Verified.		03 Mar 2021 22:14:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered '18 Jan 2021'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:04:12

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
DataPoint Verified.		03 Mar 2021 22:14:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered '0'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:04:12

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
DataPoint Verified.		03 Mar 2021 22:14:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered '98'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:04:12

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
User entered '%'	System	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:04:12

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
DataPoint Verified.		03 Mar 2021 22:14:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered '97.8' F	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:04:12

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
DataPoint Verified.		03 Mar 2021 22:14:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:04:12

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
DataPoint Verified.		03 Mar 2021 22:14:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:04:12

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
DataPoint Verified.		03 Mar 2021 22:14:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:04:12

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
DataPoint Verified.		03 Mar 2021 22:14:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:04:12

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
DataPoint Verified.		03 Mar 2021 22:14:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:04:12

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
DataPoint Verified.		03 Mar 2021 22:14:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:04:12

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
DataPoint Verified.		03 Mar 2021 22:14:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:04:12

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
DataPoint Verified.		03 Mar 2021 22:14:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:04:12

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
DataPoint Verified.		03 Mar 2021 22:14:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:04:12

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
DataPoint Verified.		03 Mar 2021 22:14:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:04:12

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
DataPoint Verified.		03 Mar 2021 22:14:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:04:12

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
DataPoint Verified.		03 Mar 2021 22:14:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:04:12

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
DataPoint Verified.		03 Mar 2021 22:14:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:04:12

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
DataPoint Verified.		03 Mar 2021 22:14:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:04:12

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
DataPoint Verified.		03 Mar 2021 22:14:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:04:12

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:38:56
DataPoint Verified.		03 Mar 2021 22:14:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:24:51

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:04:12

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:39:01
DataPoint Verified.		03 Mar 2021 22:14:49
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered '13 Jan 2021'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:25:04

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:04:12

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:39:01
DataPoint Verified.		03 Mar 2021 22:14:49
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'Yes (Y)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:25:04

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:04:12

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:39:01
DataPoint Verified.		03 Mar 2021 22:14:49
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'No (N)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:25:04

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:04:12

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:39:01
DataPoint Verified.		03 Mar 2021 22:14:49
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered '13 Jan 2021'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:25:04

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:04:12

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:39:01
DataPoint Verified.		03 Mar 2021 22:14:49
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'Nasal Swab (Nasal Swab)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:25:04

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:04:12

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:39:01
DataPoint Verified.		03 Mar 2021 22:14:49
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered empty.	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:25:04

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:04:12

[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)	02 May 2021 07:39:01
DataPoint Verified.		03 Mar 2021 22:14:49
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'No (N)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:25:04

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:04:12

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:39:01
DataPoint Verified.		03 Mar 2021 22:14:49
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered empty.	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:25:04

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:04:12

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:39:01
DataPoint Verified.		03 Mar 2021 22:14:49
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered empty.	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:25:04

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:04:12

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:39:01
User entered '0'	System	19 Jan 2021 16:25:04

US3322329

Folder: Covid-19 Assessment 13 Jan 2021

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 17:04:12

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:39:05
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 14:38:46
DataPoint Un-verified.	Elisa Moralez (b) (4)	20 Apr 2021 17:46:10
Signature has been broken.	(b) (4) Elisa Moralez (b) (4)	20 Apr 2021 17:46:10
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) Elisa Moralez (b) (4)	20 Apr 2021 17:46:10
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 22:14:53
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'No (N)'	(b) (4) Elisa Moralez (b) (4)	19 Jan 2021 16:25:13

US3322329

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 17:04:12

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:33:55
User accepted default value 'Day 3 (Day 3)'	Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:27:22

US3322329

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 17:04:12

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:33:55
DataPoint Verified.		15 Apr 2021 15:31:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'Yes (Y)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:27:22

US3322329

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 17:04:12

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:33:55
DataPoint Verified.		15 Apr 2021 15:31:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered '15 Jan 2021'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:27:22

US3322329

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 17:04:12

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:33:55
User accepted default value 'Day 5 (Day 5)'	Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:27:22

US3322329

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 17:04:12

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:33:55
DataPoint Verified.		15 Apr 2021 15:31:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'Yes (Y)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:27:22

US3322329

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 17:04:12

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:33:55
DataPoint Verified.		15 Apr 2021 15:31:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered '17 Jan 2021'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:27:22

US3322329

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 17:04:12

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:33:55
User accepted default value 'Day 7 (Day 7)'	Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:27:22

US3322329

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 17:04:12

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:33:55
DataPoint Verified.		15 Apr 2021 15:31:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:27:22

US3322329

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 17:04:12

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:33:55
DataPoint Verified.		15 Apr 2021 15:31:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered empty.	(b) (4)	
	Elisa Moralez (b) (4)	19 Jan 2021 16:27:22
	(b) (4)	

US3322329

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 17:04:12

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:33:55
User accepted default value 'Day 9 (Day 9)'	Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:27:22

US3322329

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 17:04:12

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:33:55
DataPoint Verified.		15 Apr 2021 15:31:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:27:22

US3322329

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 17:04:12

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:33:55
DataPoint Verified.		15 Apr 2021 15:31:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered empty.	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:27:22

US3322329

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 17:04:12

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:33:55
User accepted default value 'Day 14 (Day 14)'	Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:27:22

US3322329

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 17:04:12

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:33:55
DataPoint Verified.		15 Apr 2021 15:31:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:27:22

US3322329

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 17:04:12

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:33:55
DataPoint Verified.		15 Apr 2021 15:31:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered empty.	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:27:22

US3322329

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 17:04:12

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:33:55
User accepted default value 'Day 21 (Day 21)'	Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:27:22

US3322329

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 17:04:12

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:33:55
DataPoint Verified.		15 Apr 2021 15:31:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:27:22

US3322329

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 17:04:12

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:33:55
DataPoint Verified.		15 Apr 2021 15:31:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered empty.	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:27:22

US3322329

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 17:04:12

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:33:55
User accepted default value 'Day 28 (Day 28)'	Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:27:22

US3322329

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 17:04:12

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:33:55
DataPoint Verified.		15 Apr 2021 15:31:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:27:22

US3322329

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 17:04:12

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:33:55
DataPoint Verified.		15 Apr 2021 15:31:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered empty.	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:27:22

US3322329

Folder: Illness Visit (2)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 17:04:12

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:58:40

US3322329

Folder: Illness Visit (2)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 17:04:12

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:34:28
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:58:40

US3322329

Folder: Illness Visit (2)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 17:04:12

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:34:30
User entered '08 Apr 2021'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:58:40

US3322329

Folder: Illness Visit (2)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 17:04:12

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:58:40

US3322329

Folder: Illness Visit (2)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 17:04:12

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:02:58
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:58:40

US3322329

Folder: Illness Visit (2)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 17:04:12

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:02:58
User entered '10 Apr 2021'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:58:40

US3322329

Folder: Illness Visit (2)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 17:04:12

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:58:40

US3322329

Folder: Illness Visit (2)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 17:04:12

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:02:58
User entered 'NA (COVID-19 Negative) (NA)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:58:40

US3322329

Folder: Illness Visit (2)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 17:04:12

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:02:58
User entered empty.	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:58:40

US3322329

Folder: Illness Visit (2)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 17:04:12

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:58:40

US3322329

Folder: Illness Visit (2)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 17:04:12

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:02:58
User entered 'NA (COVID-19 Negative) (NA)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:58:40

US3322329

Folder: Illness Visit (2)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 17:04:12

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:02:58
User entered empty.	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:58:40

US3322329

Folder: Illness Visit (2)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 17:04:12

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:58:40

US3322329

Folder: Illness Visit (2)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 17:04:12

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:02:58
User entered 'NA (COVID-19 Negative) (NA)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:58:40

US3322329

Folder: Illness Visit (2)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 17:04:12

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:02:58
User entered empty.	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:58:40

US3322329

Folder: Illness Visit (2)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 17:04:12

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:58:40

US3322329

Folder: Illness Visit (2)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 17:04:12

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:02:58
User entered 'NA (COVID-19 Negative) (NA)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:58:40

US3322329

Folder: Illness Visit (2)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 17:04:12

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:02:58
User entered empty.	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:58:40

US3322329

Folder: Illness Visit (2)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 17:04:12

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:58:40

US3322329

Folder: Illness Visit (2)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 17:04:12

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:02:58
User entered 'NA (COVID-19 Negative) (NA)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:58:40

US3322329

Folder: Illness Visit (2)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 17:04:12

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:02:58
User entered empty.	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:58:40

US3322329

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:04:12

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:33:33
DataPoint Verified.		03 Mar 2021 21:59:34
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'Yes (Y)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:25:39

US3322329

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:04:12

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:33:33
DataPoint Verified.		03 Mar 2021 21:59:34
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered '13 Jan 2021'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:25:39

US3322329

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:04:12

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:33:33
DataPoint Verified.		03 Mar 2021 21:59:34
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'Clinic (Clinic)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:25:39

US3322329

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:04:12

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:33:33
User entered 'SICKD1'	System	19 Jan 2021 16:25:39

US3322329

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:04:12

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:33:37
DataPoint Verified.		03 Mar 2021 22:00:18
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'Yes (Y)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:26:24

US3322329

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:04:12

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:33:37
DataPoint Verified.		03 Mar 2021 22:00:18
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered '13 Jan 2021'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:26:24

US3322329

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:04:12

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:33:37
DataPoint Verified.		03 Mar 2021 22:00:18
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered '14:08'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:26:24

US3322329

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:04:12

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:33:37
User entered '13 Jan 2021 14:08'	System	19 Jan 2021 16:26:24

US3322329

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:04:12

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:33:37
DataPoint Verified.		03 Mar 2021 22:00:18
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered '73' in	(b) (4) Elisa Moralez (b) (4)	19 Jan 2021 16:26:24
DataPoint set to visible.	(b) (4) System	19 Jan 2021 16:25:39

US3322329

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:04:12

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:33:37
DataPoint Verified.		03 Mar 2021 22:00:18
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered '219' lb	(b) (4) Elisa Moralez (b) (4)	19 Jan 2021 16:26:24
DataPoint set to visible.	(b) (4) System	19 Jan 2021 16:25:39

US3322329

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:04:12

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:33:37
DataPoint Verified.		03 Mar 2021 22:00:18
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User closed query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4) (b) (4), (b) (6)	20 Jan 2021 18:23:01
Query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS per physician review' (Site from System).	Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:26:37
User opened query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	19 Jan 2021 16:26:24
User entered '96.6' F	Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:26:24

US3322329

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:04:12

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:33:37
DataPoint Verified.		03 Mar 2021 22:00:18
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'Oral (Oral)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:26:24

US3322329

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:04:12

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:33:37
DataPoint Verified.		03 Mar 2021 22:00:18
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered empty.	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:26:24

US3322329

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:04:12

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:33:37
DataPoint Verified.		03 Mar 2021 22:00:18
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered '61'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:26:24

US3322329

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:04:12

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:33:37
User entered 'bpm'	System	19 Jan 2021 16:26:24

US3322329

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:04:12

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:33:37
DataPoint Verified.		03 Mar 2021 22:00:18
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered '16'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:26:24

US3322329

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:04:12

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:33:37
User entered 'breaths/min'	System	19 Jan 2021 16:26:24

US3322329

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:04:12

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:33:37
DataPoint Verified.		03 Mar 2021 22:00:18
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered '117'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:26:24

US3322329

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:04:12

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:33:37
User entered 'mmHg'	System	19 Jan 2021 16:26:24

US3322329

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:04:12

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:33:37
DataPoint Verified.		03 Mar 2021 22:00:18
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered '80'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:26:24

US3322329

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:04:12

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:33:37
User entered 'mmHg'	System	19 Jan 2021 16:26:24

US3322329

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:04:12

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	02 May 2021 16:33:37

US3322329

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:04:12

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:33:37

US3322329

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:04:12

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:33:41
DataPoint Verified.		03 Mar 2021 22:00:27
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'Yes (Y)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:26:44

US3322329

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:04:12

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:33:41
DataPoint Verified.		03 Mar 2021 22:00:27
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered '13 Jan 2021'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:26:44

US3322329

Folder: Illness Visit Day 1 (1)

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

Generated On: 09 Jun 2021 17:04:12

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:33:45
DataPoint Verified.		03 Mar 2021 22:00:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'Yes (Y)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:26:50

US3322329

Folder: Illness Visit Day 1 (1)

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

Generated On: 09 Jun 2021 17:04:12

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:33:45
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 22:00:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User closed query 'Per Lab Recon: SARS-COV2: Sample dated 13 JAN 2021, is still missing in PPD GCL records. Please review if the sample has been shipped, if yes, then please provide the Accession number, Tracking number, shipping date in response, as this helps to track the sample with the details provided. Please also confirm if the site had scan in barcodes through Preclarus, so that the data reflects in PPD GCL records. Thank you.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 08:08:48
' (Site from DM).		
Query 'Per Lab Recon: SARS-COV2: Sample dated 13 JAN 2021, is still missing in PPD GCL records. Please review if the sample has been shipped, if yes, then please provide the Accession number, Tracking number, shipping date in response, as this helps to track the sample with the details provided. Please also confirm if the site had scan in barcodes through Preclarus, so that the data reflects in PPD GCL records. Thank you.	Elisa Moralez (b) (4) (b) (4)	01 Feb 2021 20:19:57
' answered with ' 945470631356' (Site from DM).		
User opened query 'Per Lab Recon: SARS-COV2: Sample dated 13 JAN 2021, is still missing in PPD GCL records. Please review if the sample has been shipped, if yes, then please provide the Accession number, Tracking number, shipping date in response, as this helps to track the sample with the details provided. Please also confirm if the site had scan in barcodes through Preclarus, so that the data reflects in PPD GCL records. Thank you.	(b) (4), (b) (6)	29 Jan 2021 10:18:11
' (Site from DM).		
User entered '13 Jan 2021'	Elisa Moralez (b) (4) (b) (4)	19 Jan 2021 16:26:50

US3322329

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:04:12

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:31:39
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:57:09

US3322329

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:04:12

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

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:31:39
User entered '06 Apr 2021'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:57:09

US3322329

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:04:12

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:31:39
User entered 'Clinic (Clinic)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:57:09

US3322329

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:04:12

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD1'	System	12 Apr 2021 18:57:09

US3322329

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:04:12

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:32:20
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:57:50

US3322329

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:04:12

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:32:20
User entered '06 Apr 2021'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:57:50

US3322329

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:04:12

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:32:20
User entered '09:11'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:57:50

US3322329

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:04:12

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '06 Apr 2021 09:11'	System	12 Apr 2021 18:57:50

US3322329

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:04:12

Height (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:32:20
User entered '73' in	Elisa Moralez (b) (4)	12 Apr 2021 18:57:50
DataPoint set to visible.	(b) (4) System	12 Apr 2021 18:57:09

US3322329

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:04:12

Weight (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:32:20
User entered '215' lb	Elisa Moralez (b) (4)	12 Apr 2021 18:57:50
DataPoint set to visible.	(b) (4) System	12 Apr 2021 18:57:09

US3322329

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:04:12

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:32:20
User closed query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3 Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		13 Apr 2021 16:30:34
Query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS' (Site from System).	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:57:57
User opened query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	12 Apr 2021 18:57:50
User entered '96.4' F	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:57:50

US3322329

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:04:12

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:32:20
User entered 'Oral (Oral)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:57:50

US3322329

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:04:12

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:32:20
User entered empty.	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:57:50

US3322329

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:04:12

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:32:20
User entered '60'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:57:50

US3322329

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:04:12

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	12 Apr 2021 18:57:50

US3322329

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:04:12

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:32:20
User entered '14'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:57:50

US3322329

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:04:12

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	12 Apr 2021 18:57:50

US3322329

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:04:12

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:32:20
User entered '141'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:57:50

US3322329

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:04:12

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	12 Apr 2021 18:57:50

US3322329

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:04:12

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:32:20
User entered '81'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:57:50

US3322329

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:04:12

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	12 Apr 2021 18:57:50

US3322329

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:04:12

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:33:11
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:58:05

US3322329

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:04:12

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:33:11
User entered '06 Apr 2021'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:58:05

US3322329

Folder: Illness Visit Day 1 (1)

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

Generated On: 09 Jun 2021 17:04:12

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:33:16
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:58:12

US3322329

Folder: Illness Visit Day 1 (1)

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

Generated On: 09 Jun 2021 17:04:12

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:33:16
User entered '06 Apr 2021'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:58:12

US3322329

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

Form: Visit Date

Generated On: 09 Jun 2021 17:04:12

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:13
DataPoint Verified.		03 Mar 2021 22:37:27
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'Yes (Y)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	21 Jan 2021 20:10:12

US3322329

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

Form: Visit Date

Generated On: 09 Jun 2021 17:04:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:13
DataPoint Verified.		03 Mar 2021 22:37:27
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered '21 Jan 2021'	(b) (4) Elisa Moralez (b) (4) (b) (4)	21 Jan 2021 20:10:12

US3322329

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

Form: Visit Date

Generated On: 09 Jun 2021 17:04:12

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 20:39:13
DataPoint Verified.		03 Mar 2021 22:37:27
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'Clinic (Clinic)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	21 Jan 2021 20:10:12

US3322329

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

Form: Visit Date

Generated On: 09 Jun 2021 17:04:12

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:13
User entered 'UNBLND_DECIDE'	System	21 Jan 2021 20:10:12

US3322329

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

Form: Unblinding

Generated On: 09 Jun 2021 17:04:12

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:13
DataPoint Verified.		03 Mar 2021 22:43:36
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered '21 Jan 2021'	(b) (4) Elisa Moralez (b) (4) (b) (4)	21 Jan 2021 20:10:21

US3322329

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

Form: Unblinding

Generated On: 09 Jun 2021 17:04:12

[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 20:39:13
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:08:27
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 08:57:05

US3322329

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

Form: Unblinding

Generated On: 09 Jun 2021 17:04:12

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:13
DataPoint Verified.		03 Mar 2021 22:43:36
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'Yes (Y)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	21 Jan 2021 20:10:21

US3322329

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

Form: Unblinding

Generated On: 09 Jun 2021 17:04:12

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:13
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:08:27
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 08:57:05

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

Form: Unblinding

Generated On: 09 Jun 2021 17:04:12

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:13
DataPoint Verified.		03 Mar 2021 22:43:36
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered '21 Jan 2021'	(b) (4) Elisa Moralez (b) (4) (b) (4)	21 Jan 2021 20:10:21

US3322329

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

Form: Unblinding

Generated On: 09 Jun 2021 17:04:12

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:13
DataPoint Verified.		03 Mar 2021 22:43:36
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	21 Jan 2021 20:10:21

US3322329

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

Form: Unblinding

Generated On: 09 Jun 2021 17:04:12

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:13
DataPoint Verified.		03 Mar 2021 22:43:36
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	21 Jan 2021 20:10:21

US3322329

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

Form: Unblinding

Generated On: 09 Jun 2021 17:04:12

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:13
DataPoint Verified.		03 Mar 2021 22:43:36
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	21 Jan 2021 20:10:21

US3322329

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

Form: Unblinding

Generated On: 09 Jun 2021 17:04:12

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:13
DataPoint Verified.		03 Mar 2021 22:43:36
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'No (N)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	21 Jan 2021 20:10:21

US3322329

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

Form: Unblinding

Generated On: 09 Jun 2021 17:04:12

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:13
User entered empty.	System	21 Jan 2021 20:10:21

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

Form: Unblinding

Generated On: 09 Jun 2021 17:04:12

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:13
User entered empty.	System	21 Jan 2021 20:10:21

US3322329

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:04:12

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:13
DataPoint Verified.		03 Mar 2021 22:44:04
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'Yes (Y)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	21 Jan 2021 20:10:27

US3322329

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:04:12

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:13
DataPoint Verified.		03 Mar 2021 22:44:04
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered '21 Jan 2021'	(b) (4) Elisa Moralez (b) (4) (b) (4)	21 Jan 2021 20:10:27

US3322329

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:04:12

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:13
DataPoint Verified.		03 Mar 2021 22:44:04
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered '13:42'	(b) (4) Elisa Moralez (b) (4) (b) (4)	21 Jan 2021 20:10:27

US3322329

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:04:12

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:13
User entered '21 Jan 2021 13:42'	System	21 Jan 2021 20:10:27

US3322329

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:04:12

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:13
DataPoint Verified.		03 Mar 2021 22:44:14
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered 'Yes (Y)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	21 Jan 2021 20:10:35

US3322329

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:04:12

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:13
DataPoint Verified.		03 Mar 2021 22:44:14
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered '21 Jan 2021'	(b) (4) Elisa Moralez (b) (4) (b) (4)	21 Jan 2021 20:10:35

US3322329

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:04:12

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:13
DataPoint Verified.		03 Mar 2021 22:44:14
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User entered '13:37'	(b) (4) Elisa Moralez (b) (4) (b) (4)	21 Jan 2021 20:10:35

US3322329

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:04:12

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:13
User entered '21 Jan 2021 13:37'	System	21 Jan 2021 20:10:35

US3322329

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 17:04:12

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:32:30
User closed query 'Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Per subject's diary, Muscle aches all over lasted beyond day 7 post injection. Please reconcile and enter event as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked. ' (Site from DM).		20 Apr 2021 15:46:16
Query 'Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Per subject's diary, Muscle aches all over lasted beyond day 7 post injection. Please reconcile and enter event as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked. ' answered with 'updated, thanks' (Site from DM).	Elisa Moralez (b) (4) (b) (4)	19 Apr 2021 20:27:21
User opened query 'Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Per subject's diary, Muscle aches all over lasted beyond day 7 post injection. Please reconcile and enter event as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked. ' (Site from DM).	(b) (4), (b) (6)	17 Apr 2021 08:41:24
User closed query 'Upper Respiratory Infection from 11Jan21 to 14Jan21 is captured in source. Please add to EDC. ' (Site from CRA).	(b) (4), (b) (6)	23 Mar 2021 03:00:54
Query 'Upper Respiratory Infection from 11Jan21 to 14Jan21 is captured in source. Please add to EDC. ' answered with 'updating now, thank you' (Site from CRA).	Elisa Moralez (b) (4) (b) (4)	09 Mar 2021 21:52:34
User opened query 'Upper Respiratory Infection from 11Jan21 to 14Jan21 is captured in source. Please add to EDC. ' (Site from CRA).	(b) (4), (b) (6)	03 Mar 2021 22:03:24

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 17:04:12

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:06:05
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	21 Oct 2020 20:06:29

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:04:12

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:05:51
Reviewed for Safety.		22 Oct 2020 18:43:09
User entered 'USA-US060-2020-mRNA-1273-P301000006'	System	22 Oct 2020 18:43:06
User entered 'New'	(b) (4), (b) (6)	22 Oct 2020 18:43:06

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:04:12

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:05:51
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: General signs and symptoms NEC, PT: Swelling face, LLT: Facial swelling - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Oct 2020 20:10:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Oct 2020 20:10:40
Data point term sent to Coder	System	21 Oct 2020 20:09:47
User entered 'Facial Swelling'	Elisa Moralez (b) (4) (b) (4)	21 Oct 2020 20:08:50

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:04:12

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:05:51
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	21 Oct 2020 20:08:50

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:04:12

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:05:51
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	21 Oct 2020 20:08:50

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:04:12

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:05:51
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	21 Oct 2020 20:08:50

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:04:12

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:05:51
User entered '17 Oct 2020'	Elisa Moralez (b) (4) (b) (4)	21 Oct 2020 20:08:50

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:04:12

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:05:51
User entered empty.	Elisa Moralez (b) (4) (b) (4)	21 Oct 2020 20:08:50

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:04:12

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 20:08:50

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:04:12

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:05:51
User entered 'No (N)' reason for change: New Information	Frances Saubon (b) (4) (b) (4)	30 Oct 2020 22:23:45
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	21 Oct 2020 20:08:50

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:04:12

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:55:44
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).		02 Nov 2020 22:14:25
DataPoint Verified.		02 Nov 2020 22:05:51
Comment added 'Query "Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct" was inadvertently closed, site will reflect data changes once available.'	Frances Saubon (b) (4) (b) (4)	30 Oct 2020 22:27:39
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 'updated' (Site from Safety).	Frances Saubon (b) (4) (b) (4)	30 Oct 2020 22:25:15
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered with 'updated' (Site from System).	Frances Saubon (b) (4) (b) (4)	30 Oct 2020 22:24:02
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	30 Oct 2020 22:23:45
User entered '22 Oct 2020' reason for change: New Information	Frances Saubon (b) (4) (b) (4)	30 Oct 2020 22:23:45
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)	30 Oct 2020 21:57:33
User entered empty.	Elisa Moralez (b) (4) (b) (4)	21 Oct 2020 20:08:50

US3322329

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:04:12

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:05:51
User entered empty.	Elisa Moralez (b) (4) (b) (4)	21 Oct 2020 20:08:50

US3322329

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:04:12

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 20:08:50

US3322329

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:04:12

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:05:51
User entered 'Grade 3/Severe (Grade 3/Severe)'	Elisa Moralez (b) (4) (b) (4)	21 Oct 2020 20:08:50

US3322329

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:04:12

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:05:51
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	21 Oct 2020 20:19:03
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	21 Oct 2020 20:08:50
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	21 Oct 2020 20:08:50

US3322329

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:04:12

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:05:51
User entered '0'	Elisa Moralez (b) (4) (b) (4)	21 Oct 2020 20:08:50

US3322329

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:04:12

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:05:51
User entered '0'	Elisa Moralez (b) (4) (b) (4)	21 Oct 2020 20:08:50

US3322329

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:04:12

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:05:51
User entered '0'	Elisa Moralez (b) (4) (b) (4)	21 Oct 2020 20:08:50

US3322329

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:04:12

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:05:51
User entered empty.	Elisa Moralez (b) (4) (b) (4)	21 Oct 2020 20:08:50

US3322329

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:04:12

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:05:51
User entered empty.	Elisa Moralez (b) (4) (b) (4)	21 Oct 2020 20:08:50

US3322329

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:04:12

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:05:51
User entered empty.	Elisa Moralez (b) (4) (b) (4)	21 Oct 2020 20:08:50

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Folder: Adverse Events

Form: Adverse Events (1)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:05:51
User entered empty.	Elisa Moralez (b) (4) (b) (4)	21 Oct 2020 20:08:50

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:04:12

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:05:51
User entered '0'	Elisa Moralez (b) (4) (b) (4)	21 Oct 2020 20:08:50

US3322329

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:04:12

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:05:51
User entered '0'	Elisa Moralez (b) (4) (b) (4)	21 Oct 2020 20:08:50

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Folder: Adverse Events

Form: Adverse Events (1)

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:05:51
User entered '1' reason for change: Data Entry Error	Blessing Felix-Okoroji (b) (4)	21 Oct 2020 20:19:03
User entered '0'	Elisa Moralez (b) (4) (b) (4)	21 Oct 2020 20:08:50

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:04:12

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:05:51
User entered 'Related (RELATED)'	Elisa Moralez (b) (4) (b) (4)	21 Oct 2020 20:08:50

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:04:12

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:05:51
User entered 'Not Related (NOT RELATED)'	Elisa Moralez (b) (4) (b) (4)	21 Oct 2020 20:08:50

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:04:12

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:05:51
User entered 'Not Applicable (NOT APPLICABLE)'	Elisa Moralez (b) (4) (b) (4)	21 Oct 2020 20:08:50

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:04:12

None

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:05:51
User entered '0'	Elisa Moralez (b) (4) (b) (4)	21 Oct 2020 20:08:50

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:04:12

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:05:51
User entered 'I'	Elisa Moralez (b) (4) (b) (4)	21 Oct 2020 20:08:50

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:04:12

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:05:51
User entered '0'	Elisa Moralez (b) (4) (b) (4)	21 Oct 2020 20:08:50

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:04:12

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 04:15:31
DataPoint Un-verified.	Elisa Moralez (b) (4) (b) (4)	13 Nov 2020 20:22:52
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	Elisa Moralez (b) (4) (b) (4)	13 Nov 2020 20:22:52
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:05:51
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Elisa Moralez (b) (4) (b) (4)	21 Oct 2020 20:08:50

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:04:12

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

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:05:51
User entered empty.	Elisa Moralez (b) (4) (b) (4)	21 Oct 2020 20:08:50

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:04:12

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 04:15:30
User closed query 'PV Query: Please provide any clinical assessment/notes concerning the subject's facial swelling from the healthcare provider who prescribed treatment for the condition with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query open until records have been provided. If the records cannot be obtained, please state so in your response.' (Site from Safety).		09 Nov 2020 15:27:52
Query 'PV Query: Please provide any clinical assessment/notes concerning the subject's facial swelling from the healthcare provider who prescribed treatment for the condition with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query open until records have been provided. If the records cannot be obtained, please state so in your response.' answered with 'Records have been sent 06-Nov-2020.' (Site from Safety).	Frances Saubon (b) (4) (b) (4)	07 Nov 2020 03:37:54
Comment added 'The IP is believed to have triggered an inflammatory response de novo or potentiated an underlying microscopic inflammatory response. We will contact subject again for further details and request medical records. Once further information is available, SAE will be updated.'	Frances Saubon (b) (4) (b) (4)	03 Nov 2020 15:35:11
Comment added 'Since the subject developed facial swelling almost two weeks after the procedure and only 2 days after receiving IP injection, the temporal relationship provides reasonable probability of causal relationship between the subject's facial swelling and receipt of IP.'	Frances Saubon (b) (4) (b) (4)	03 Nov 2020 15:34:50
Comment added 'CONTINUATION: However, I also believe if the facial swelling was solely due to the cosmetic procedure, it would have occurred before IP administration on 15 OCT 2020.'	Frances Saubon (b) (4) (b) (4)	03 Nov 2020 15:34:08
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	03 Nov 2020 15:31:50

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:04:12

[Narrative](#)

Audit	User	Time (GMT)
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	03 Nov 2020 15:31:50
User entered 'SAE term: Facial swelling; Intensity: Severe; Causality: Considered IP related given it occurred on Day 3 of observation period post-vaccination. The prior cosmetic procedure believed to have been a contributing factor but not the cause since the procedure was almost 2 weeks before the facial swelling. A safety call was made on 20 OCT 2020 due to patient reporting grade 3 injection site swelling. Subject confirmed experiencing injection site swelling/hardness measuring 125mm on day 3 which came down to 55mm by day 4. She experienced mild deltoid tenderness but did not have any trouble moving the affected arm. During this safety call, the subject reported receiving medical attention on 17 October 2020 due to facial swelling. Patient stated she got dermal filler (Voluma -crosslinked hyaluronic acid) cosmetic injections in cheeks on 02 Oct 2020 prior to receiving second IP. It was a planned procedure, and she forgot to mention it when she came onsite for her second vaccine on 15 OCT 2020. During her visit 2, the physical exam was normal including skin. Patient stated she developed bilateral facial swelling (left greater than right) the night of 17 Oct 2020. She contacted the doctor that did the cosmetic procedure, and she was prescribed Prednisolone for 5 days. She took prednisolone 25mg on 17 Oct 2020 at 10 am and prednisolone 40mg daily thereafter. On 20 Oct 2020, the facial swelling was almost completely resolved with only minimal swelling under the left eye. The reason she called her doctor and the reason for treatment with prednisolone was the facial swelling not IP injection site swelling. Facial swelling is a potential side-effect of Voluma dermal filler topical injections, and I believe the injection of dermal filler was a contributing factor to the patient developing facial swelling.' reason for change: New Information	Frances Saubon (b) (4) (b) (4)	03 Nov 2020 15:31:50

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:04:12

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	03 Nov 2020 15:27:09
DataPoint Un-verified.	Frances Saubon (b) (4)	03 Nov 2020 15:27:09
User entered empty; reason for change New Information	(b) (4)	03 Nov 2020 15:27:09
DataPoint Verified.	Frances Saubon (b) (4)	03 Nov 2020 15:27:09
	(b) (4)	
	(b) (4), (b) (6)	02 Nov 2020 22:05:51
User opened query 'PV Query: Please provide any clinical assessment/notes concerning the subject's facial swelling from the healthcare provider who prescribed treatment for the condition with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query open until records have been provided. If the records cannot be obtained, please state so in your response.' (Site from Safety).		30 Oct 2020 21:57:44
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	21 Oct 2020 20:21:22
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	21 Oct 2020 20:21:22

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:04:12

[Narrative](#)

Audit	User	Time (GMT)
User entered 'per physician "Considered IP related given it occurred on Day 3 of observation period post-vaccination. A safety call was made on 20 Oct 2020 due to patient reporting grade 3 injection site swelling. Subject confirmed experiencing injection site swelling/hardness measuring 125mm on day 3 which came down to 55mm by day 4. She experienced mild deltoid tenderness but did not have any trouble moving the affected arm. During safety call, the subject reported receiving medical attention 17 Oct 2020 due to facial swelling. Patient stated she got dermal filler cosmetic injections in cheeks on 02 Oct 2020 prior to receiving second IP. It was a planned procedure, and she forgot to mention it when she came onsite for her second vaccine on 15 Oct 2020. During her visit 2, the physical exam was normal including skin. Patient stated she developed bilateral facial swelling (left greater than right) the night of 17 Oct 2020. She contacted the doctor that did the cosmetic procedure, and she was prescribed Prednisolone for 5 days. She took prednisolone 25 mg on 17 Oct 2020 at 10 am and prednisolone 40mg daily thereafter. On 20 Oct 2020, the facial swelling was almost completely resolved with only minimal swelling under the left eyes. The reason she called her doctor and the reason for treatment with prednisolone was the facial swelling not IP injection site swelling. Facial swelling is a potential side-effect of Voluma dermal filler topical injections and I believe the injection of dermal filler was a contributing factor to the patient developing facial swelling. However, I also believe if the facial swelling was solely due to the cosmetic procedure, it would have occurred before IP administration on 15 Oct 2020. Since subject developed facial swelling almost two weeks after the procedure and only 2 days after IP injection, the temporal relationship provides reasonable probability of causal relationship between the subject's facial swelling and receipt of IP..." reason for change: Per Query Resolution	Elisa Morales (b) (4)	21 Oct 2020 20:21:22

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:04:12

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	21 Oct 2020 20:08:50
User entered empty.	Elisa Moralez (b) (4) (b) (4)	21 Oct 2020 20:08:50

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:04:12

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Oct 2020 20:08:50

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:04:12

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	21 Oct 2020 20:08:50

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:04:12

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:56

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:04:12

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:56
DataPoint Verified.	Heather Davis (b) (4)	08 Apr 2021 18:04:26
User signature succeeded.	(b) (4)	
	Veronica Fragoso (b) (4)	31 Mar 2021 23:58:32
	(b) (4)	
User coded data point as SOC: General disorders and administration site conditions, HLGT: Administration site reactions, HLT: Injection site reactions, PT: Injection site swelling, LLT: Injection site swelling - version MedDRA\\23.0.	Coder Import (b) (4)	09 Mar 2021 21:54:41
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	09 Mar 2021 21:54:41
	(b) (4)	
Data point term sent to Coder	System	09 Mar 2021 21:53:58
User entered 'Left arm injection site swelling'	Elisa Moralez (b) (4)	09 Mar 2021 21:53:20
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:04:12

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:56
DataPoint Verified.	Heather Davis (b) (4)	08 Apr 2021 18:04:26
User signature succeeded.	(b) (4) Veronica Fragoso (b) (4)	31 Mar 2021 23:58:32
User entered 'No (N)'	(b) (4) Elisa Moralez (b) (4)	09 Mar 2021 21:53:20
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:04:12

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:56
DataPoint Verified.	Heather Davis (b) (4)	08 Apr 2021 18:04:26
User signature succeeded.	(b) (4) Veronica Fragoso (b) (4)	31 Mar 2021 23:58:32
User entered 'Yes (Y)'	(b) (4) Elisa Moralez (b) (4)	09 Mar 2021 21:53:20
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:04:12

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:56
DataPoint Verified.	Heather Davis (b) (4)	08 Apr 2021 18:04:26
User signature succeeded.	(b) (4) Veronica Fragoso (b) (4)	31 Mar 2021 23:58:32
User entered 'No (N)'	(b) (4) Elisa Moralez (b) (4)	09 Mar 2021 21:53:20
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:04:12

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:56
DataPoint Verified.	Heather Davis (b) (4)	08 Apr 2021 18:04:26
User signature succeeded.	(b) (4)	
	Veronica Fragoso (b) (4)	31 Mar 2021 23:58:32
User closed query 'Per DM CLR: Please note that this AE start date does not match the Diary initial start date of Solicited Symptom INJECTION SITE SWELLING on 15OCT2020. Please review if this should be reconciled. Else, provide clarification on dates.	(b) (4)	
' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 15:46:47
Query 'Per DM CLR: Please note that this AE start date does not match the Diary initial start date of Solicited Symptom INJECTION SITE SWELLING on 15OCT2020. Please review if this should be reconciled. Else, provide clarification on dates.	Elisa Moralez (b) (4)	25 Mar 2021 21:49:42
' answered with 'updated' (Site from DM).	(b) (4)	
User entered '15 Oct 2020' reason for change: Data Entry Error	Elisa Moralez (b) (4)	25 Mar 2021 21:49:21
User opened query 'Per DM CLR: Please note that this AE start date does not match the Diary initial start date of Solicited Symptom INJECTION SITE SWELLING on 15OCT2020. Please review if this should be reconciled. Else, provide clarification on dates.	(b) (4)	
' (Site from DM).	(b) (4), (b) (6)	24 Mar 2021 04:00:02
User entered '16 Oct 2020'	Elisa Moralez (b) (4)	09 Mar 2021 21:53:20
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:04:12

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:56
DataPoint Verified.	Heather Davis (b) (4)	08 Apr 2021 18:04:26
User signature succeeded.	(b) (4)	
	Veronica Fragoso (b) (4)	31 Mar 2021 23:58:32
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	
	(b) (4), (b) (6)	10 Mar 2021 16:58:14
Query 'Data is required. Please provide.' answered with 'UNK:UNK in source' (Site from System).	Elisa Moralez (b) (4)	09 Mar 2021 21:55:38
	(b) (4)	
User opened query 'Data is required. Please provide.' (Site from System).	System	09 Mar 2021 21:53:20
User entered empty.	Elisa Moralez (b) (4)	09 Mar 2021 21:53:20
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:04:12

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:56
User entered empty.	System	09 Mar 2021 21:53:20

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:04:12

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:56
DataPoint Verified.	Heather Davis (b) (4)	08 Apr 2021 18:04:26
User signature succeeded.	(b) (4) Veronica Fragoso (b) (4)	31 Mar 2021 23:58:32
User entered 'No (N)'	(b) (4) Elisa Moralez (b) (4)	09 Mar 2021 21:53:20
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:04:12

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:56
DataPoint Verified.	Heather Davis (b) (4)	08 Apr 2021 18:04:26
User signature succeeded.	(b) (4) Veronica Fragoso (b) (4)	31 Mar 2021 23:58:32
User entered '22 Oct 2020'	(b) (4) Elisa Moralez (b) (4)	09 Mar 2021 21:53:20
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:04:12

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:56
DataPoint Verified.	Heather Davis (b) (4)	08 Apr 2021 18:04:26
User signature succeeded.	(b) (4)	
	Veronica Fragoso (b) (4)	31 Mar 2021 23:58:32
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	
	(b) (4), (b) (6)	10 Mar 2021 16:58:16
Query 'Data is required. Please provide.' answered with 'UNK:UNK in source' (Site from System).	Elisa Moralez (b) (4)	09 Mar 2021 21:55:37
	(b) (4)	
User opened query 'Data is required. Please provide.' (Site from System).	System	09 Mar 2021 21:53:20
User entered empty.	Elisa Moralez (b) (4)	09 Mar 2021 21:53:20
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:04:12

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:56
User entered empty.	System	09 Mar 2021 21:53:20

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:04:12

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:56
DataPoint Verified.	Heather Davis (b) (4)	08 Apr 2021 18:04:26
User signature succeeded.	(b) (4) Veronica Fragoso (b) (4)	31 Mar 2021 23:58:32
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Elisa Moralez (b) (4)	09 Mar 2021 21:53:20

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:04:12

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:56
DataPoint Verified.	Heather Davis (b) (4)	08 Apr 2021 18:04:26
User signature succeeded.	(b) (4) Veronica Fragoso (b) (4)	31 Mar 2021 23:58:32
User entered 'No (N)'	(b) (4) Elisa Moralez (b) (4)	09 Mar 2021 21:53:20
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:04:12

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:56
DataPoint Verified.	Heather Davis (b) (4)	08 Apr 2021 18:04:26
User signature succeeded.	(b) (4) Veronica Fragoso (b) (4)	31 Mar 2021 23:58:32
User entered '0'	(b) (4) Elisa Moralez (b) (4)	09 Mar 2021 21:53:20
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:04:12

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:56
DataPoint Verified.	Heather Davis (b) (4)	08 Apr 2021 18:04:26
User signature succeeded.	(b) (4) Veronica Fragoso (b) (4)	31 Mar 2021 23:58:32
User entered '0'	(b) (4) Elisa Moralez (b) (4)	09 Mar 2021 21:53:20
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:04:12

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:56
DataPoint Verified.	Heather Davis (b) (4)	08 Apr 2021 18:04:26
User signature succeeded.	(b) (4)	31 Mar 2021 23:58:32
User entered '0'	Veronica Fragoso (b) (4)	09 Mar 2021 21:53:20
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:04:12

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:56
DataPoint Verified.	Heather Davis (b) (4)	08 Apr 2021 18:04:26
User signature succeeded.	(b) (4) Veronica Fragoso (b) (4)	31 Mar 2021 23:58:32
User entered empty.	(b) (4) Elisa Moralez (b) (4)	09 Mar 2021 21:53:20
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:04:12

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:56
DataPoint Verified.	Heather Davis (b) (4)	08 Apr 2021 18:04:26
User signature succeeded.	(b) (4)	31 Mar 2021 23:58:32
User entered empty.	Veronica Fragoso (b) (4)	09 Mar 2021 21:53:20
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:04:12

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:56
DataPoint Verified.	Heather Davis (b) (4)	08 Apr 2021 18:04:26
User signature succeeded.	(b) (4) Veronica Fragoso (b) (4)	31 Mar 2021 23:58:32
User entered empty.	(b) (4) Elisa Moralez (b) (4)	09 Mar 2021 21:53:20
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:04:12

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:56
DataPoint Verified.	Heather Davis (b) (4)	08 Apr 2021 18:04:26
User signature succeeded.	(b) (4) Veronica Fragoso (b) (4)	31 Mar 2021 23:58:32
User entered empty.	(b) (4) Elisa Moralez (b) (4)	09 Mar 2021 21:53:20
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:04:12

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:56
DataPoint Verified.	Heather Davis (b) (4)	08 Apr 2021 18:04:26
User signature succeeded.	(b) (4) Veronica Fragoso (b) (4)	31 Mar 2021 23:58:32
User entered '0'	(b) (4) Elisa Moralez (b) (4)	09 Mar 2021 21:53:20
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:04:12

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:56
DataPoint Verified.	Heather Davis (b) (4)	08 Apr 2021 18:04:26
User signature succeeded.	(b) (4) Veronica Fragoso (b) (4)	31 Mar 2021 23:58:32
User entered '0'	(b) (4) Elisa Moralez (b) (4)	09 Mar 2021 21:53:20
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:04:12

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:56
DataPoint Verified.	Heather Davis (b) (4)	08 Apr 2021 18:04:26
User signature succeeded.	(b) (4) Veronica Fragoso (b) (4)	31 Mar 2021 23:58:32
User entered '0'	(b) (4) Elisa Moralez (b) (4)	09 Mar 2021 21:53:20
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:04:12

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:56
DataPoint Verified.	Heather Davis (b) (4)	08 Apr 2021 18:04:26
User signature succeeded.	(b) (4) Veronica Fragoso (b) (4)	31 Mar 2021 23:58:32
User entered 'Related (RELATED)'	(b) (4) Elisa Moralez (b) (4)	09 Mar 2021 21:53:20

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:04:12

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:56
DataPoint Verified.	Heather Davis (b) (4)	08 Apr 2021 18:04:26
User signature succeeded.	(b) (4) Veronica Fragoso (b) (4)	31 Mar 2021 23:58:32
User entered 'Not Related (NOT RELATED)'	(b) (4) Elisa Moralez (b) (4)	09 Mar 2021 21:53:20

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:04:12

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:56
DataPoint Verified.	Heather Davis (b) (4)	08 Apr 2021 18:04:26
User signature succeeded.	(b) (4)	
	Veronica Fragoso (b) (4)	31 Mar 2021 23:58:32
User closed query 'Per CDM: "Action taken with investigational product" is recorded as 'None', however if Adverse Event started after IP then it expected to be as "Not applicable" instead of "None". Thank you' (Site from DM).	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 16:09:10
Query 'Per CDM: "Action taken with investigational product" is recorded as 'None', however if Adverse Event started after IP then it expected to be as "Not applicable" instead of "None". Thank you' answered with 'updated' (Site from DM).	Elisa Moralez (b) (4)	23 Mar 2021 19:17:31
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Elisa Moralez (b) (4)	23 Mar 2021 19:17:28
	(b) (4)	
User opened query 'Per CDM: "Action taken with investigational product" is recorded as 'None', however if Adverse Event started after IP then it expected to be as "Not applicable" instead of "None". Thank you' (Site from DM).	(b) (4), (b) (6)	18 Mar 2021 19:57:26
User entered 'None (NONE)'	Elisa Moralez (b) (4)	09 Mar 2021 21:53:20
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:04:12

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:56
DataPoint Verified.	Heather Davis (b) (4)	08 Apr 2021 18:04:26
User signature succeeded.	(b) (4) Veronica Fragoso (b) (4)	31 Mar 2021 23:58:32
User entered '0'	(b) (4) Elisa Moralez (b) (4)	09 Mar 2021 21:53:20
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:04:12

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:56
DataPoint Verified.	Heather Davis (b) (4)	08 Apr 2021 18:04:26
User signature succeeded.	(b) (4) Veronica Fragoso (b) (4)	31 Mar 2021 23:58:32
User entered 'l'	(b) (4) Elisa Moralez (b) (4)	09 Mar 2021 21:53:20
	(b) (4)	

US3322329

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:04:12

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:56
DataPoint Verified.	Heather Davis (b) (4)	08 Apr 2021 18:04:26
User signature succeeded.	(b) (4) Veronica Fragoso (b) (4)	31 Mar 2021 23:58:32
User entered '0'	(b) (4) Elisa Moralez (b) (4)	09 Mar 2021 21:53:20
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:04:12

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:56
DataPoint Verified.	Heather Davis (b) (4)	08 Apr 2021 18:04:26
User signature succeeded.	(b) (4) Veronica Fragoso (b) (4)	31 Mar 2021 23:58:32
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	09 Mar 2021 21:53:20

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:04:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:56
DataPoint Verified.	Heather Davis (b) (4)	08 Apr 2021 18:04:26
User signature succeeded.	(b) (4) Veronica Fragoso (b) (4)	31 Mar 2021 23:58:32
User entered empty.	(b) (4) Elisa Moralez (b) (4)	09 Mar 2021 21:53:20
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:04:12

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:56
DataPoint Verified.	Heather Davis (b) (4)	08 Apr 2021 18:04:26
User signature succeeded.	(b) (4) Veronica Fragoso (b) (4)	31 Mar 2021 23:58:32
User entered empty.	(b) (4) Elisa Moralez (b) (4)	09 Mar 2021 21:53:20
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:04:12

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:56
User entered '0'	System	09 Mar 2021 21:53:20

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:04:12

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:56
User entered '0'	System	09 Mar 2021 21:53:20

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:04:12

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:56

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:04:12

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:39

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:04:12

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:39
DataPoint Verified.	Heather Davis (b) (4)	08 Apr 2021 18:04:26
User signature succeeded.	(b) (4)	
	Veronica Fragoso (b) (4)	31 Mar 2021 23:58:32
	(b) (4)	
User coded data point as SOC: General disorders and administration site conditions, HLGT: Administration site reactions, HLT: Injection site reactions, PT: Injection site pain, LLT: Injection site tenderness - version MedDRA\\23.0.	Coder Import (b) (4)	12 Mar 2021 14:07:06
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	(b) (4)	12 Mar 2021 14:07:06
Data point term sent to Coder	System	09 Mar 2021 21:55:00
User entered 'left arm injection site tenderness'	Elisa Moralez (b) (4)	09 Mar 2021 21:54:08
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:04:12

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:39
DataPoint Verified.	Heather Davis (b) (4)	08 Apr 2021 18:04:26
User signature succeeded.	(b) (4) Veronica Fragoso (b) (4)	31 Mar 2021 23:58:32
User entered 'Yes (Y)'	(b) (4) Elisa Moralez (b) (4)	09 Mar 2021 21:54:08

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:04:12

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:39
DataPoint Verified.	Heather Davis (b) (4)	08 Apr 2021 18:04:26
User signature succeeded.	(b) (4) Veronica Fragoso (b) (4)	31 Mar 2021 23:58:32
User entered 'No (N)'	(b) (4) Elisa Moralez (b) (4)	09 Mar 2021 21:54:08
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:04:12

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:39
DataPoint Verified.	Heather Davis (b) (4)	08 Apr 2021 18:04:26
User signature succeeded.	(b) (4) Veronica Fragoso (b) (4)	31 Mar 2021 23:58:32
User entered 'No (N)'	(b) (4) Elisa Moralez (b) (4)	09 Mar 2021 21:54:08

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:04:12

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:39
DataPoint Verified.	Heather Davis (b) (4)	08 Apr 2021 18:04:26
User signature succeeded.	(b) (4)	
	Veronica Fragoso (b) (4)	31 Mar 2021 23:58:32
	(b) (4)	
User entered '17 Nov 2020'	Elisa Moralez (b) (4)	09 Mar 2021 21:54:08
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:04:12

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:39
DataPoint Verified.	Heather Davis (b) (4)	08 Apr 2021 18:04:26
User signature succeeded.	(b) (4) Veronica Fragoso (b) (4)	31 Mar 2021 23:58:32
User entered empty.	(b) (4) Elisa Moralez (b) (4)	09 Mar 2021 21:54:08
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:04:12

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:39
User entered empty.	System	09 Mar 2021 21:54:08

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:04:12

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:39
DataPoint Verified.	Heather Davis (b) (4)	08 Apr 2021 18:04:26
User signature succeeded.	(b) (4) Veronica Fragoso (b) (4)	31 Mar 2021 23:58:32
User entered 'No (N)'	(b) (4) Elisa Moralez (b) (4)	09 Mar 2021 21:54:08
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:04:12

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:39
DataPoint Verified.	Heather Davis (b) (4)	08 Apr 2021 18:04:26
User signature succeeded.	(b) (4) Veronica Fragoso (b) (4)	31 Mar 2021 23:58:32
User entered '01 Dec 2020'	(b) (4) Elisa Moralez (b) (4)	09 Mar 2021 21:54:08
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:04:12

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:39
DataPoint Verified.	Heather Davis (b) (4)	08 Apr 2021 18:04:26
User signature succeeded.	(b) (4) Veronica Fragoso (b) (4)	31 Mar 2021 23:58:32
User entered empty.	(b) (4) Elisa Moralez (b) (4)	09 Mar 2021 21:54:08
	(b) (4)	

US3322329

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:04:12

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:39
User entered empty.	System	09 Mar 2021 21:54:08

US3322329

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:04:12

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:39
DataPoint Verified.	Heather Davis (b) (4)	08 Apr 2021 18:04:26
User signature succeeded.	(b) (4) Veronica Fragoso (b) (4)	31 Mar 2021 23:58:32
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Elisa Moralez (b) (4)	09 Mar 2021 21:54:08

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:04:12

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:39
DataPoint Verified.	Heather Davis (b) (4)	08 Apr 2021 18:04:26
User signature succeeded.	(b) (4) Veronica Fragoso (b) (4)	31 Mar 2021 23:58:32
User entered 'No (N)'	(b) (4) Elisa Moralez (b) (4)	09 Mar 2021 21:54:08
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:04:12

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:39
DataPoint Verified.	Heather Davis (b) (4)	08 Apr 2021 18:04:26
User signature succeeded.	(b) (4) Veronica Fragoso (b) (4)	31 Mar 2021 23:58:32
User entered '0'	(b) (4) Elisa Moralez (b) (4)	09 Mar 2021 21:54:08
	(b) (4)	

US3322329

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:04:12

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:39
DataPoint Verified.	Heather Davis (b) (4)	08 Apr 2021 18:04:26
User signature succeeded.	(b) (4) Veronica Fragoso (b) (4)	31 Mar 2021 23:58:32
User entered '0'	(b) (4) Elisa Moralez (b) (4)	09 Mar 2021 21:54:08
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:04:12

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:39
DataPoint Verified.	Heather Davis (b) (4)	08 Apr 2021 18:04:26
User signature succeeded.	(b) (4) Veronica Fragoso (b) (4)	31 Mar 2021 23:58:32
User entered '0'	(b) (4) Elisa Moralez (b) (4)	09 Mar 2021 21:54:08

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:04:12

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:39
DataPoint Verified.	Heather Davis (b) (4)	08 Apr 2021 18:04:26
User signature succeeded.	(b) (4) Veronica Fragoso (b) (4)	31 Mar 2021 23:58:32
User entered empty.	(b) (4) Elisa Moralez (b) (4)	09 Mar 2021 21:54:08
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:04:12

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:39
DataPoint Verified.	Heather Davis (b) (4)	08 Apr 2021 18:04:26
User signature succeeded.	(b) (4)	31 Mar 2021 23:58:32
User entered empty.	Veronica Fragoso (b) (4)	09 Mar 2021 21:54:08
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:04:12

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:39
DataPoint Verified.	Heather Davis (b) (4)	08 Apr 2021 18:04:26
User signature succeeded.	(b) (4) Veronica Fragoso (b) (4)	31 Mar 2021 23:58:32
User entered empty.	(b) (4) Elisa Moralez (b) (4)	09 Mar 2021 21:54:08
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:04:12

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:39
DataPoint Verified.	Heather Davis (b) (4)	08 Apr 2021 18:04:26
User signature succeeded.	(b) (4) Veronica Fragoso (b) (4)	31 Mar 2021 23:58:32
User entered empty.	(b) (4) Elisa Moralez (b) (4)	09 Mar 2021 21:54:08
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:04:12

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:39
DataPoint Verified.	Heather Davis (b) (4)	08 Apr 2021 18:04:26
User signature succeeded.	(b) (4) Veronica Fragoso (b) (4)	31 Mar 2021 23:58:32
User entered '0'	(b) (4) Elisa Moralez (b) (4)	09 Mar 2021 21:54:08

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:04:12

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:39
DataPoint Verified.	Heather Davis (b) (4)	08 Apr 2021 18:04:26
User signature succeeded.	(b) (4) Veronica Fragoso (b) (4)	31 Mar 2021 23:58:32
User entered '0'	(b) (4) Elisa Moralez (b) (4)	09 Mar 2021 21:54:08
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:04:12

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:39
DataPoint Verified.	Heather Davis (b) (4)	08 Apr 2021 18:04:26
User signature succeeded.	(b) (4) Veronica Fragoso (b) (4)	31 Mar 2021 23:58:32
User entered '0'	(b) (4) Elisa Moralez (b) (4)	09 Mar 2021 21:54:08
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:04:12

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:39
DataPoint Verified.	Heather Davis (b) (4)	08 Apr 2021 18:04:26
User signature succeeded.	(b) (4) Veronica Fragoso (b) (4)	31 Mar 2021 23:58:32
User entered 'Related (RELATED)'	(b) (4) Elisa Moralez (b) (4)	09 Mar 2021 21:54:08

US3322329

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:04:12

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:39
DataPoint Verified.	Heather Davis (b) (4)	08 Apr 2021 18:04:26
User signature succeeded.	(b) (4) Veronica Fragoso (b) (4)	31 Mar 2021 23:58:32
User entered 'Related (RELATED)'	(b) (4) Elisa Moralez (b) (4)	09 Mar 2021 21:54:08

US3322329

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:04:12

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:39
DataPoint Verified.	Heather Davis (b) (4)	08 Apr 2021 18:04:26
User signature succeeded.	(b) (4) Veronica Fragoso (b) (4)	31 Mar 2021 23:58:32
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Elisa Moralez (b) (4)	09 Mar 2021 21:54:08

US3322329

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:04:12

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:39
DataPoint Verified.	Heather Davis (b) (4)	08 Apr 2021 18:04:26
User signature succeeded.	(b) (4) Veronica Fragoso (b) (4)	31 Mar 2021 23:58:32
User entered 'l'	(b) (4) Elisa Moralez (b) (4)	09 Mar 2021 21:54:08
	(b) (4)	

US3322329

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:04:12

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:39
DataPoint Verified.	Heather Davis (b) (4)	08 Apr 2021 18:04:26
User signature succeeded.	(b) (4) Veronica Fragoso (b) (4)	31 Mar 2021 23:58:32
User entered '0'	(b) (4) Elisa Moralez (b) (4)	09 Mar 2021 21:54:08
	(b) (4)	

US3322329

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:04:12

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:39
DataPoint Verified.	Heather Davis (b) (4)	08 Apr 2021 18:04:26
User signature succeeded.	(b) (4) Veronica Fragoso (b) (4)	31 Mar 2021 23:58:32
User entered '0'	(b) (4) Elisa Moralez (b) (4)	09 Mar 2021 21:54:08
	(b) (4)	

US3322329

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:04:12

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:39
DataPoint Verified.	Heather Davis (b) (4)	08 Apr 2021 18:04:26
User signature succeeded.	(b) (4) Veronica Fragoso (b) (4)	31 Mar 2021 23:58:32
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	09 Mar 2021 21:54:08

US3322329

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:04:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:39
DataPoint Verified.	Heather Davis (b) (4)	08 Apr 2021 18:04:26
User signature succeeded.	(b) (4) Veronica Fragoso (b) (4)	31 Mar 2021 23:58:32
User entered empty.	(b) (4) Elisa Moralez (b) (4)	09 Mar 2021 21:54:08
	(b) (4)	

US3322329

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:04:12

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:39
DataPoint Verified.	Heather Davis (b) (4)	08 Apr 2021 18:04:26
User signature succeeded.	(b) (4) Veronica Fragoso (b) (4)	31 Mar 2021 23:58:32
User entered empty.	(b) (4) Elisa Moralez (b) (4)	09 Mar 2021 21:54:08
	(b) (4)	

US3322329

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:04:12

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:39
User entered '0'	System	09 Mar 2021 21:54:08

US3322329

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:04:12

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:39
User entered 'I'	System	09 Mar 2021 21:54:08

US3322329

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:04:12

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:39

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:04:12

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:28

US3322329

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:04:12

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:28
DataPoint Verified.	Heather Davis (b) (4)	08 Apr 2021 18:04:26
User signature succeeded.	(b) (4)	
	Veronica Fragoso (b) (4)	31 Mar 2021 23:58:32
User closed query 'Per MM, please confirm if this is not COVID-19. If not, update the AE term to reflect the causative organism, if known. ' (Site from DM).	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 14:46:35
Query 'Per MM, please confirm if this is not COVID-19. If not, update the AE term to reflect the causative organism, if known. ' answered with 'UNKNOWN' (Site from DM).	Elisa Moralez (b) (4)	29 Mar 2021 22:27:38
	(b) (4)	
User opened query 'Per MM, please confirm if this is not COVID-19. If not, update the AE term to reflect the causative organism, if known. ' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 10:02:05
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Upper respiratory tract infection, LLT: Upper respiratory infection - version MedDRA\\23.0.	Coder Import (b) (4)	09 Mar 2021 21:55:41
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	09 Mar 2021 21:55:41
	(b) (4)	
Data point term sent to Coder	System	09 Mar 2021 21:55:00
User entered 'Upper Respiratory Infection'	Elisa Moralez (b) (4)	09 Mar 2021 21:54:37
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:04:12

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:28
DataPoint Verified.	Heather Davis (b) (4)	08 Apr 2021 18:04:26
User signature succeeded.	(b) (4) Veronica Fragoso (b) (4)	31 Mar 2021 23:58:32
User entered 'Yes (Y)'	(b) (4) Elisa Moralez (b) (4)	09 Mar 2021 21:54:37

US3322329

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:04:12

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:28
DataPoint Verified.	Heather Davis (b) (4)	08 Apr 2021 18:04:26
User signature succeeded.	(b) (4) Veronica Fragoso (b) (4)	31 Mar 2021 23:58:32
User entered 'No (N)'	(b) (4) Elisa Moralez (b) (4)	09 Mar 2021 21:54:37
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:04:12

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:28
DataPoint Verified.	Heather Davis (b) (4)	08 Apr 2021 18:04:26
User signature succeeded.	(b) (4) Veronica Fragoso (b) (4)	31 Mar 2021 23:58:32
User entered 'No (N)'	(b) (4) Elisa Moralez (b) (4)	09 Mar 2021 21:54:37
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:04:12

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:28
DataPoint Verified.	Heather Davis (b) (4)	08 Apr 2021 18:04:26
User signature succeeded.	(b) (4) Veronica Fragoso (b) (4)	31 Mar 2021 23:58:32
User entered '11 Jan 2021'	(b) (4) Elisa Moralez (b) (4)	09 Mar 2021 21:54:37
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:04:12

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:28
DataPoint Verified.	Heather Davis (b) (4)	08 Apr 2021 18:04:26
User signature succeeded.	(b) (4) Veronica Fragoso (b) (4)	31 Mar 2021 23:58:32
User entered empty.	(b) (4) Elisa Moralez (b) (4)	09 Mar 2021 21:54:37
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:04:12

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:28
User entered empty.	System	09 Mar 2021 21:54:37

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:04:12

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:28
DataPoint Verified.	Heather Davis (b) (4)	08 Apr 2021 18:04:26
User signature succeeded.	(b) (4) Veronica Fragoso (b) (4)	31 Mar 2021 23:58:32
User entered 'No (N)'	(b) (4) Elisa Moralez (b) (4)	09 Mar 2021 21:54:37
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:04:12

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:28
DataPoint Verified.	Heather Davis (b) (4)	08 Apr 2021 18:04:26
User signature succeeded.	(b) (4) Veronica Fragoso (b) (4)	31 Mar 2021 23:58:32
User entered '14 Jan 2021'	(b) (4) Elisa Moralez (b) (4)	09 Mar 2021 21:54:37

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:04:12

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:28
DataPoint Verified.	Heather Davis (b) (4)	08 Apr 2021 18:04:26
User signature succeeded.	(b) (4) Veronica Fragoso (b) (4)	31 Mar 2021 23:58:32
User entered empty.	(b) (4) Elisa Moralez (b) (4)	09 Mar 2021 21:54:37
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:04:12

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:28
User entered empty.	System	09 Mar 2021 21:54:37

US3322329

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:04:12

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:28
DataPoint Verified.	Heather Davis (b) (4)	08 Apr 2021 18:04:26
User signature succeeded.	(b) (4) Veronica Fragoso (b) (4)	31 Mar 2021 23:58:32
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Elisa Moralez (b) (4)	09 Mar 2021 21:54:37

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:04:12

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:28
DataPoint Verified.	Heather Davis (b) (4)	08 Apr 2021 18:04:26
User signature succeeded.	(b) (4) Veronica Fragoso (b) (4)	31 Mar 2021 23:58:32
User entered 'No (N)'	(b) (4) Elisa Moralez (b) (4)	09 Mar 2021 21:54:37
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:04:12

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:28
DataPoint Verified.	Heather Davis (b) (4)	08 Apr 2021 18:04:26
User signature succeeded.	(b) (4) Veronica Fragoso (b) (4)	31 Mar 2021 23:58:32
User entered '0'	(b) (4) Elisa Moralez (b) (4)	09 Mar 2021 21:54:37
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:04:12

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:28
DataPoint Verified.	Heather Davis (b) (4)	08 Apr 2021 18:04:26
User signature succeeded.	(b) (4) Veronica Fragoso (b) (4)	31 Mar 2021 23:58:32
User entered '0'	(b) (4) Elisa Moralez (b) (4)	09 Mar 2021 21:54:37
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:04:12

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:28
DataPoint Verified.	Heather Davis (b) (4)	08 Apr 2021 18:04:26
User signature succeeded.	(b) (4)	31 Mar 2021 23:58:32
User entered '0'	Veronica Fragoso (b) (4)	09 Mar 2021 21:54:37
	(b) (4)	
	Elisa Moralez (b) (4)	
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:04:12

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:28
DataPoint Verified.	Heather Davis (b) (4)	08 Apr 2021 18:04:26
User signature succeeded.	(b) (4) Veronica Fragoso (b) (4)	31 Mar 2021 23:58:32
User entered empty.	(b) (4) Elisa Moralez (b) (4)	09 Mar 2021 21:54:37
	(b) (4)	

US3322329

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:04:12

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:28
DataPoint Verified.	Heather Davis (b) (4)	08 Apr 2021 18:04:26
User signature succeeded.	(b) (4) Veronica Fragoso (b) (4)	31 Mar 2021 23:58:32
User entered empty.	(b) (4) Elisa Moralez (b) (4)	09 Mar 2021 21:54:37
	(b) (4)	

US3322329

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:04:12

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:28
DataPoint Verified.	Heather Davis (b) (4)	08 Apr 2021 18:04:26
User signature succeeded.	(b) (4) Veronica Fragoso (b) (4)	31 Mar 2021 23:58:32
User entered empty.	(b) (4) Elisa Moralez (b) (4)	09 Mar 2021 21:54:37
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:04:12

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:28
DataPoint Verified.	Heather Davis (b) (4)	08 Apr 2021 18:04:26
User signature succeeded.	(b) (4) Veronica Fragoso (b) (4)	31 Mar 2021 23:58:32
User entered empty.	(b) (4) Elisa Moralez (b) (4)	09 Mar 2021 21:54:37
	(b) (4)	

US3322329

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:04:12

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:28
DataPoint Verified.	Heather Davis (b) (4)	08 Apr 2021 18:04:26
User signature succeeded.	(b) (4) Veronica Fragoso (b) (4)	31 Mar 2021 23:58:32
User entered '0'	(b) (4) Elisa Moralez (b) (4)	09 Mar 2021 21:54:37

US3322329

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:04:12

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:28
DataPoint Verified.	Heather Davis (b) (4)	08 Apr 2021 18:04:26
User signature succeeded.	(b) (4) Veronica Fragoso (b) (4)	31 Mar 2021 23:58:32
User entered '0'	(b) (4) Elisa Moralez (b) (4)	09 Mar 2021 21:54:37
	(b) (4)	

US3322329

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:04:12

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:28
DataPoint Verified.	Heather Davis (b) (4)	08 Apr 2021 18:04:26
User signature succeeded.	(b) (4) Veronica Fragoso (b) (4)	31 Mar 2021 23:58:32
User entered '0'	(b) (4) Elisa Moralez (b) (4)	09 Mar 2021 21:54:37
	(b) (4)	

US3322329

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:04:12

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:28
DataPoint Verified.	Heather Davis (b) (4)	08 Apr 2021 18:04:26
User signature succeeded.	(b) (4) Veronica Fragoso (b) (4)	31 Mar 2021 23:58:32
User entered 'Not Related (NOT RELATED)'	(b) (4) Elisa Moralez (b) (4)	09 Mar 2021 21:54:37

US3322329

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:04:12

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:28
DataPoint Verified.	Heather Davis (b) (4)	08 Apr 2021 18:04:26
User signature succeeded.	(b) (4) Veronica Fragoso (b) (4)	31 Mar 2021 23:58:32
User entered 'Not Related (NOT RELATED)'	(b) (4) Elisa Moralez (b) (4)	09 Mar 2021 21:54:37

US3322329

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:04:12

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:28
DataPoint Verified.	Heather Davis (b) (4)	08 Apr 2021 18:04:26
User signature succeeded.	(b) (4) Veronica Fragoso (b) (4)	31 Mar 2021 23:58:32
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Elisa Moralez (b) (4)	09 Mar 2021 21:54:37

US3322329

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:04:12

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:28
DataPoint Verified.	Heather Davis (b) (4)	08 Apr 2021 18:04:26
User signature succeeded.	(b) (4) Veronica Fragoso (b) (4)	31 Mar 2021 23:58:32
User entered 'l'	(b) (4) Elisa Moralez (b) (4)	09 Mar 2021 21:54:37
	(b) (4)	

US3322329

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:04:12

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:28
DataPoint Verified.	Heather Davis (b) (4)	08 Apr 2021 18:04:26
User signature succeeded.	(b) (4) Veronica Fragoso (b) (4)	31 Mar 2021 23:58:32
User entered '0'	(b) (4) Elisa Moralez (b) (4)	09 Mar 2021 21:54:37
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:04:12

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:28
DataPoint Verified.	Heather Davis (b) (4)	08 Apr 2021 18:04:26
User signature succeeded.	(b) (4) Veronica Fragoso (b) (4)	31 Mar 2021 23:58:32
User entered '0'	(b) (4) Elisa Moralez (b) (4)	09 Mar 2021 21:54:37
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:04:12

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:28
DataPoint Verified.	Heather Davis (b) (4)	08 Apr 2021 18:04:26
User signature succeeded.	(b) (4) Veronica Fragoso (b) (4)	31 Mar 2021 23:58:32
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	09 Mar 2021 21:54:37

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:04:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:28
DataPoint Verified.	Heather Davis (b) (4)	08 Apr 2021 18:04:26
User signature succeeded.	(b) (4) Veronica Fragoso (b) (4)	31 Mar 2021 23:58:32
User entered empty.	(b) (4) Elisa Moralez (b) (4)	09 Mar 2021 21:54:37
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:04:12

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:28
DataPoint Verified.	Heather Davis (b) (4)	08 Apr 2021 18:04:26
User signature succeeded.	(b) (4) Veronica Fragoso (b) (4)	31 Mar 2021 23:58:32
User entered empty.	(b) (4) Elisa Moralez (b) (4)	09 Mar 2021 21:54:37
	(b) (4)	

US3322329

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:04:12

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:28
User entered '0'	System	09 Mar 2021 21:54:37

US3322329

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:04:12

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:28
User entered 'I'	System	09 Mar 2021 21:54:37

US3322329

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:04:12

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:28

US3322329

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:04:12

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	28 Apr 2021 16:20:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:07:41
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Upper respiratory tract infection, LLT: Upper respiratory infection - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Apr 2021 20:27:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Apr 2021 20:27:40
Data point term sent to Coder	System	19 Apr 2021 20:26:16
User entered 'Upper Respiratory Infection'	Elisa Moralez (b) (4) (b) (4)	19 Apr 2021 20:25:40

US3322329

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:04:12

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	28 Apr 2021 16:20:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:07:41
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	19 Apr 2021 20:25:40

US3322329

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:04:12

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	28 Apr 2021 16:20:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:07:41
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	19 Apr 2021 20:25:40

US3322329

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:04:12

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	28 Apr 2021 16:20:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:07:41
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	19 Apr 2021 20:25:40

US3322329

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:04:12

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	28 Apr 2021 16:20:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:07:41
User entered '29 Mar 2021'	Elisa Moralez (b) (4) (b) (4)	19 Apr 2021 20:25:40

US3322329

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:04:12

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	28 Apr 2021 16:20:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:07:41
User entered empty.	Elisa Moralez (b) (4) (b) (4)	19 Apr 2021 20:25:40

US3322329

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:04:12

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Apr 2021 20:25:40

US3322329

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:04:12

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	28 Apr 2021 16:20:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:07:41
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	19 Apr 2021 20:25:40

US3322329

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:04:12

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	28 Apr 2021 16:20:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:07:41
User entered '06 Apr 2021'	Elisa Moralez (b) (4) (b) (4)	19 Apr 2021 20:25:40

US3322329

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:04:12

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	28 Apr 2021 16:20:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:07:41
User entered empty.	Elisa Moralez (b) (4) (b) (4)	19 Apr 2021 20:25:40

US3322329

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:04:12

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Apr 2021 20:25:40

US3322329

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:04:12

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	28 Apr 2021 16:20:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:07:41
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Elisa Moralez (b) (4) (b) (4)	19 Apr 2021 20:25:40

US3322329

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:04:12

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	28 Apr 2021 16:20:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:07:41
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	19 Apr 2021 20:25:40

US3322329

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:04:12

Death

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	28 Apr 2021 16:20:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:07:41
User entered '0'	Elisa Moralez (b) (4) (b) (4)	19 Apr 2021 20:25:40

US3322329

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:04:12

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	28 Apr 2021 16:20:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:07:41
User entered '0'	Elisa Moralez (b) (4) (b) (4)	19 Apr 2021 20:25:40

US3322329

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:04:12

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	28 Apr 2021 16:20:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:07:41
User entered '0'	Elisa Moralez (b) (4) (b) (4)	19 Apr 2021 20:25:40

US3322329

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:04:12

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	28 Apr 2021 16:20:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:07:41
User entered empty.	Elisa Moralez (b) (4) (b) (4)	19 Apr 2021 20:25:40

US3322329

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:04:12

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	28 Apr 2021 16:20:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:07:41
User entered empty.	Elisa Moralez (b) (4) (b) (4)	19 Apr 2021 20:25:40

US3322329

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:04:12

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	28 Apr 2021 16:20:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:07:41
User entered empty.	Elisa Moralez (b) (4) (b) (4)	19 Apr 2021 20:25:40

US3322329

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:04:12

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	28 Apr 2021 16:20:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:07:41
User entered empty.	Elisa Moralez (b) (4) (b) (4)	19 Apr 2021 20:25:40

US3322329

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:04:12

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	28 Apr 2021 16:20:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:07:41
User entered '0'	Elisa Moralez (b) (4) (b) (4)	19 Apr 2021 20:25:40

US3322329

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:04:12

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	28 Apr 2021 16:20:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:07:41
User entered '0'	Elisa Moralez (b) (4) (b) (4)	19 Apr 2021 20:25:40

US3322329

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:04:12

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	28 Apr 2021 16:20:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:07:41
User entered '0'	Elisa Moralez (b) (4) (b) (4)	19 Apr 2021 20:25:40

US3322329

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:04:12

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	28 Apr 2021 16:20:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:07:41
User entered 'Not Related (NOT RELATED)'	Elisa Moralez (b) (4) (b) (4)	19 Apr 2021 20:25:40

US3322329

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:04:12

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	28 Apr 2021 16:20:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:07:41
User entered 'Not Related (NOT RELATED)'	Elisa Moralez (b) (4) (b) (4)	19 Apr 2021 20:25:40

US3322329

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:04:12

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	28 Apr 2021 16:20:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:07:41
User entered 'Not Applicable (NOT APPLICABLE)'	Elisa Moralez (b) (4) (b) (4)	19 Apr 2021 20:25:40

US3322329

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:04:12

None

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	28 Apr 2021 16:20:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:07:41
User entered '0'	Elisa Moralez (b) (4) (b) (4)	19 Apr 2021 20:25:40

US3322329

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:04:12

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	28 Apr 2021 16:20:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:07:41
User entered 'I'	Elisa Moralez (b) (4) (b) (4)	19 Apr 2021 20:25:40

US3322329

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:04:12

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	28 Apr 2021 16:20:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:07:41
User entered '0'	Elisa Moralez (b) (4) (b) (4)	19 Apr 2021 20:25:40

US3322329

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:04:12

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	28 Apr 2021 16:20:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:07:41
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Elisa Moralez (b) (4) (b) (4)	19 Apr 2021 20:25:40

US3322329

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:04:12

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

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	28 Apr 2021 16:20:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:07:41
User entered empty.	Elisa Moralez (b) (4) (b) (4)	19 Apr 2021 20:25:40

US3322329

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:04:12

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	28 Apr 2021 16:20:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:07:41
User entered empty.	Elisa Moralez (b) (4) (b) (4)	19 Apr 2021 20:25:40

US3322329

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:04:12

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	19 Apr 2021 20:25:40

US3322329

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:04:12

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	19 Apr 2021 20:25:40

US3322329

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:04:12

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:14

US3322329

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:04:12

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:14
User signature succeeded.	Veronica Fragoso (b) (4)	28 Apr 2021 16:20:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:05:45
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Muscle disorders, HLT: Muscle pains, PT: Myalgia, LLT: Myalgia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Apr 2021 20:27:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Apr 2021 20:27:43
Data point term sent to Coder	System	19 Apr 2021 20:27:19
User entered 'Generalized Myalgia'	Elisa Moralez (b) (4) (b) (4)	19 Apr 2021 20:26:25

US3322329

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:04:12

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:14
User signature succeeded.	Veronica Fragoso (b) (4)	28 Apr 2021 16:20:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:05:45
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	19 Apr 2021 20:26:25

US3322329

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:04:12

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:14
User signature succeeded.	Veronica Fragoso (b) (4)	28 Apr 2021 16:20:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:05:45
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	19 Apr 2021 20:26:25

US3322329

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:04:12

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:14
User signature succeeded.	Veronica Fragoso (b) (4)	28 Apr 2021 16:20:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:05:45
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	19 Apr 2021 20:26:25

US3322329

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:04:12

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:14
User signature succeeded.	Veronica Fragoso (b) (4)	28 Apr 2021 16:20:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:05:45
User entered '16 Sep 2020'	Elisa Moralez (b) (4) (b) (4)	19 Apr 2021 20:26:25

US3322329

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:04:12

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:14
User signature succeeded.	Veronica Fragoso (b) (4)	28 Apr 2021 16:20:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:05:45
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	19 Apr 2021 20:26:36
User entered empty; reason for change Data Entry Error	Elisa Moralez (b) (4) (b) (4)	19 Apr 2021 20:26:36
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	19 Apr 2021 20:26:25
User entered '21:26'	Elisa Moralez (b) (4) (b) (4)	19 Apr 2021 20:26:25

US3322329

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:04:12

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:14
User entered empty.	System	19 Apr 2021 20:26:36
User entered '16 Sep 2020 21:26'	System	19 Apr 2021 20:26:25

US3322329

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:04:12

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:14
User signature succeeded.	Veronica Fragoso (b) (4)	28 Apr 2021 16:20:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:05:45
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	19 Apr 2021 20:26:25

US3322329

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:04:12

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:14
User signature succeeded.	Veronica Fragoso (b) (4)	28 Apr 2021 16:20:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:05:45
User entered '19 Sep 2020'	Elisa Moralez (b) (4) (b) (4)	19 Apr 2021 20:26:25

US3322329

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:04:12

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:14
User signature succeeded.	Veronica Fragoso (b) (4)	28 Apr 2021 16:20:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:05:45
User closed query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	19 Apr 2021 20:26:36
User entered empty; reason for change Data Entry Error	Elisa Moralez (b) (4) (b) (4)	19 Apr 2021 20:26:36
User opened query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	19 Apr 2021 20:26:25
User entered '12:35'	Elisa Moralez (b) (4) (b) (4)	19 Apr 2021 20:26:25

US3322329

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:04:12

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:14
User entered empty.	System	19 Apr 2021 20:26:36
User entered '19 Sep 2020 12:35'	System	19 Apr 2021 20:26:25

US3322329

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:04:12

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:14
User signature succeeded.	Veronica Fragoso (b) (4)	28 Apr 2021 16:20:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:05:45
User entered 'Grade 1/Mild (Grade 1/Mild)'	Elisa Moralez (b) (4) (b) (4)	19 Apr 2021 20:26:25

US3322329

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:04:12

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:14
User signature succeeded.	Veronica Fragoso (b) (4)	28 Apr 2021 16:20:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:05:45
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	19 Apr 2021 20:26:25

US3322329

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:04:12

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:14
User signature succeeded.	Veronica Fragoso (b) (4)	28 Apr 2021 16:20:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:05:45
User entered '0'	Elisa Moralez (b) (4) (b) (4)	19 Apr 2021 20:26:25

US3322329

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:04:12

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:14
User signature succeeded.	Veronica Fragoso (b) (4)	28 Apr 2021 16:20:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:05:45
User entered '0'	Elisa Moralez (b) (4) (b) (4)	19 Apr 2021 20:26:25

US3322329

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:04:12

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:14
User signature succeeded.	Veronica Fragoso (b) (4)	28 Apr 2021 16:20:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:05:45
User entered '0'	Elisa Moralez (b) (4) (b) (4)	19 Apr 2021 20:26:25

US3322329

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:04:12

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:14
User signature succeeded.	Veronica Fragoso (b) (4)	28 Apr 2021 16:20:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:05:45
User entered empty.	Elisa Moralez (b) (4) (b) (4)	19 Apr 2021 20:26:25

US3322329

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:04:12

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:14
User signature succeeded.	Veronica Fragoso (b) (4)	28 Apr 2021 16:20:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:05:45
User entered empty.	Elisa Moralez (b) (4) (b) (4)	19 Apr 2021 20:26:25

US3322329

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:04:12

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:14
User signature succeeded.	Veronica Fragoso (b) (4)	28 Apr 2021 16:20:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:05:45
User entered empty.	Elisa Moralez (b) (4) (b) (4)	19 Apr 2021 20:26:25

US3322329

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:04:12

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:14
User signature succeeded.	Veronica Fragoso (b) (4)	28 Apr 2021 16:20:35
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:05:45
User entered empty.	Elisa Moralez (b) (4)	19 Apr 2021 20:26:25

US3322329

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:04:12

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:14
User signature succeeded.	Veronica Fragoso (b) (4)	28 Apr 2021 16:20:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:05:45
User entered '0'	Elisa Moralez (b) (4) (b) (4)	19 Apr 2021 20:26:25

US3322329

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:04:12

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:14
User signature succeeded.	Veronica Fragoso (b) (4)	28 Apr 2021 16:20:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:05:45
User entered '0'	Elisa Moralez (b) (4) (b) (4)	19 Apr 2021 20:26:25

US3322329

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:04:12

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:14
User signature succeeded.	Veronica Fragoso (b) (4)	28 Apr 2021 16:20:35
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:05:45
User entered '0'	Elisa Moralez (b) (4)	19 Apr 2021 20:26:25

US3322329

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:04:12

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:14
User signature succeeded.	Veronica Fragoso (b) (4)	28 Apr 2021 16:20:35
User closed query 'Per MM: As this event is captured as a solicited AR, please review the relationship to IP and update, if applicable. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Apr 2021 13:56:04
DataPoint Verified.		23 Apr 2021 17:49:41
Query 'Per MM: As this event is captured as a solicited AR, please review the relationship to IP and update, if applicable. ' answered with 'reviewed and updated, thank you!' (Site from DM).	Elisa Moralez (b) (4) (b) (4)	23 Apr 2021 16:50:19
DataPoint Un-verified.	Elisa Moralez (b) (4) (b) (4)	23 Apr 2021 16:50:09
User entered 'Related (RELATED)' reason for change: Data Entry Error	Elisa Moralez (b) (4)	23 Apr 2021 16:50:09
User opened query 'Per MM: As this event is captured as a solicited AR, please review the relationship to IP and update, if applicable. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Apr 2021 11:51:16
DataPoint Verified.		20 Apr 2021 17:05:45
User entered 'Not Related (NOT RELATED)'	Elisa Moralez (b) (4) (b) (4)	19 Apr 2021 20:26:25

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:04:12

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:14
User signature succeeded.	Veronica Fragoso (b) (4)	28 Apr 2021 16:20:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:05:45
User entered 'Not Applicable (NOT APPLICABLE)'	Elisa Moralez (b) (4) (b) (4)	19 Apr 2021 20:26:25

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:04:12

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:14
User signature succeeded.	Veronica Fragoso (b) (4)	28 Apr 2021 16:20:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:05:45
User entered 'None (NONE)'	Elisa Moralez (b) (4) (b) (4)	19 Apr 2021 20:26:25

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:04:12

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:14
User signature succeeded.	Veronica Fragoso (b) (4)	28 Apr 2021 16:20:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:05:45
User entered '0'	Elisa Moralez (b) (4) (b) (4)	19 Apr 2021 20:26:25

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:04:12

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:14
User signature succeeded.	Veronica Fragoso (b) (4)	28 Apr 2021 16:20:35
User closed query 'Please confirm conmeds as no conmed is listed in source with this indication. Please confirm and update accordingly.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:17:00
Query 'Please confirm conmeds as no conmed is listed in source with this indication. Please confirm and update accordingly.' answered with 'updated, thank you' (Site from CRA).	Elisa Moralez (b) (4) (b) (4)	21 Apr 2021 14:15:45
User opened query 'Please confirm conmeds as no conmed is listed in source with this indication. Please confirm and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	20 Apr 2021 17:11:10
DataPoint Verified.		20 Apr 2021 17:05:45
User entered 'I'	Elisa Moralez (b) (4) (b) (4)	19 Apr 2021 20:26:25

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:04:12

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:14
User signature succeeded.	Veronica Fragoso (b) (4)	28 Apr 2021 16:20:35
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:05:45
User entered '0'	Elisa Moralez (b) (4)	19 Apr 2021 20:26:25

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:04:12

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:14
User signature succeeded.	Veronica Fragoso (b) (4)	28 Apr 2021 16:20:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:05:45
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Elisa Moralez (b) (4) (b) (4)	19 Apr 2021 20:26:25

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:04:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:14
User signature succeeded.	Veronica Fragoso (b) (4)	28 Apr 2021 16:20:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:05:45
User entered empty.	Elisa Moralez (b) (4) (b) (4)	19 Apr 2021 20:26:25

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:04:12

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:14
User signature succeeded.	Veronica Fragoso (b) (4)	28 Apr 2021 16:20:35
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:05:45
User entered empty.	Elisa Moralez (b) (4)	19 Apr 2021 20:26:25

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:04:12

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:14
User entered '0'	System	19 Apr 2021 20:26:25

US3322329

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:04:12

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:14
User entered '0'	System	19 Apr 2021 20:26:25

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:04:12

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:01:14

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:04:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:32:30
User closed query 'Per source Amoxicillin/Clavulanic acid was taken 17Oct20 to 21Nov20. 875/125 mg BID. Please confirm with source and update accordingly.' (Site from CRA).		23 Mar 2021 03:02:46
Query 'Per source Amoxicillin/Clavulanic acid was taken 17Oct20 to 21Nov20. 875/125 mg BID. Please confirm with source and update accordingly.' answered with 'updated to match source, thank you' (Site from CRA).	Elisa Moralez (b) (4) (b) (4)	09 Mar 2021 21:58:40
User opened query 'Per source Amoxicillin/Clavulanic acid was taken 17Oct20 to 21Nov20. 875/125 mg BID. Please confirm with source and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	03 Mar 2021 22:35:03
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:38:14
User closed query 'Per CDM: According to a "Diary Dose 2", medication was taken to treat pain or fever, however no corresponding CM is entered. Please consider entering corresponding CM or clarify otherwise. Thank you!' (Site from DM).		26 Oct 2020 18:29:56
Query 'Per CDM: According to a "Diary Dose 2", medication was taken to treat pain or fever, however no corresponding CM is entered. Please consider entering corresponding CM or clarify otherwise. Thank you!' answered with 'naproxen is entered in conmeds toward this entry' (Site from DM).	Elisa Moralez (b) (4) (b) (4)	23 Oct 2020 15:22:03
User opened query 'Per CDM: According to a "Diary Dose 2", medication was taken to treat pain or fever, however no corresponding CM is entered. Please consider entering corresponding CM or clarify otherwise. Thank you!' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 05:50:51
User entered 'Yes (Y)'		17 Sep 2020 21:22:29

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:04:12

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:58:48
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: NAPROXEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Apr 2021 14:17:04
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Apr 2021 14:17:04
Data point term sent to Coder Coding entries removed.	System Elisa Moralez (b) (4) (b) (4)	21 Apr 2021 14:15:57 21 Apr 2021 14:15:36
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:03:38
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: NAPROXEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Oct 2020 16:53:21
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Oct 2020 16:53:21
Data point term sent to Coder Coding entries removed.	System Elisa Moralez (b) (4) (b) (4)	30 Oct 2020 16:52:46 30 Oct 2020 16:51:51
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: NAPROXEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Sep 2020 05:48:46

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:04:12

[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 User entered 'NAPROXEN'	Coder Import (b) (4) (b) (4) System (b) (4), (b) (6)	18 Sep 2020 05:48:46 17 Sep 2020 21:33:43 17 Sep 2020 21:32:41

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:04:12

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:58:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	02 Nov 2020 22:03:38
User entered 'No (N)'		17 Sep 2020 21:32:41

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:04:12

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:58:48
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 14:37:54
DataPoint Un-verified.	Elisa Moralez (b) (4)	21 Apr 2021 14:15:36
Signature has been broken.	(b) (4) Elisa Moralez (b) (4)	21 Apr 2021 14:15:36
User entered 'generalized myalgia' reason for change: New Information	Elisa Moralez (b) (4)	21 Apr 2021 14:15:36
User signature succeeded.	(b) (4) Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the SORE MUSCLES is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of SORE MUSCLES did not meet the AE reporting criteria ' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Nov 2020 19:37:55
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:03:38

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:04:12

[Indication](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the SORE MUSCLES is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of SORE MUSCLES did not meet the AE reporting criteria ' answered with 'this does not meet the requirements for AE reporting and was reported less than 4 days after IP from vaccine 2' (Site from DM).	Elisa Moralez (b) (4)	30 Oct 2020 16:52:38
User entered 'muscle pain' reason for change: New Information	Elisa Moralez (b) (4)	30 Oct 2020 16:51:51
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the SORE MUSCLES is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of SORE MUSCLES did not meet the AE reporting criteria	(b) (4), (b) (6)	30 Oct 2020 10:51:09
' (Site from DM). User entered 'SORE MUSCLES'	(b) (4), (b) (6)	17 Sep 2020 21:32:41

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:04:12

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:58:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (D) (4), (b) (6)	02 Nov 2020 22:03:38
User entered '500'		17 Sep 2020 21:32:41

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:04:12

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:58:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	02 Nov 2020 22:03:38
User entered 'mg (mg)'		17 Sep 2020 21:32:41

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:04:12

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:58:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:03:38
User entered empty.		17 Sep 2020 21:32:41

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:04:12

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:58:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:03:38
User entered 'once (ONCE)'		17 Sep 2020 21:32:41

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:04:12

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:58:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:03:38
User entered empty.		17 Sep 2020 21:32:41

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:04:12

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:58:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:03:38
User entered 'Oral (ORAL)'		17 Sep 2020 21:32:41

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:04:12

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:58:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:03:38
User entered empty.		17 Sep 2020 21:32:41

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:04:12

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:58:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:03:38
User entered '16 Sep 2020'		17 Sep 2020 21:32:41

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:04:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:58:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:03:38
User entered '0'		17 Sep 2020 21:32:41

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:04:12

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:58:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:03:38
User entered 'No (N)'		17 Sep 2020 21:32:41

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:04:12

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:58:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:03:38
User entered '16 Sep 2020'		17 Sep 2020 21:32:41

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:04:12

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:58:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:03:38
User entered 'Yes (Y)'		17 Sep 2020 21:32:41

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:04:12

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:58:48
User entered empty.	System	17 Sep 2020 21:32:41

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:04:12

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:58:48
User entered empty.	System	17 Sep 2020 21:32:41

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:04:12

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:58:48
User entered empty.	System	17 Sep 2020 21:32:41

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:04:12

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: ESTROGENS, ATC: NATURAL AND SEMISYNTHETIC ESTROGENS, PLAIN, PRODUCT: ESTRADIOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Nov 2020 17:55:07
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Nov 2020 17:55:07
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:03:38
Data point term sent to Coder	System	02 Nov 2020 16:44:33
Coding entries removed.	Elisa Moralez (b) (4)	02 Nov 2020 16:43:58
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: ESTROGENS, ATC: NATURAL AND SEMISYNTHETIC ESTROGENS, PLAIN, PRODUCT: ESTRADIOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Sep 2020 04:26:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Sep 2020 04:26:41
Data point term sent to Coder	System	26 Sep 2020 19:08:54
User entered 'Estradiol pellet'	Elisa Moralez (b) (4)	26 Sep 2020 19:08:04

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:04:12

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:03:38
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	26 Sep 2020 19:08:04

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:04:12

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User closed query 'Per DM CLR : Please note that Con Med indication should reflect a medical condition instead of what the drug does. Please review and update the Con Med indication with the corresponding AE or Med History eCRF so there is an appropriate match. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Nov 2020 19:36:43
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:03:38
Query 'Per DM CLR : Please note that Con Med indication should reflect a medical condition instead of what the drug does. Please review and update the Con Med indication with the corresponding AE or Med History eCRF so there is an appropriate match. ' answered with 'updated' (Site from DM).	Elisa Moralez (b) (4) (b) (4)	02 Nov 2020 16:44:06
User entered 'post menopausal' reason for change: New Information	Elisa Moralez (b) (4) (b) (4)	02 Nov 2020 16:43:58
User opened query 'Per DM CLR : Please note that Con Med indication should reflect a medical condition instead of what the drug does. Please review and update the Con Med indication with the corresponding AE or Med History eCRF so there is an appropriate match. ' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 10:50:54
User entered 'Hormone replacement therapy'	Elisa Moralez (b) (4) (b) (4)	26 Sep 2020 19:08:04

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:04:12

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:03:38
User entered '25'	Elisa Moralez (b) (4) (b) (4)	26 Sep 2020 19:08:04

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:04:12

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:03:38
User entered 'mg (mg)'	Elisa Moralez (b) (4) (b) (4)	26 Sep 2020 19:08:04

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:04:12

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:03:38
User entered empty.	Elisa Moralez (b) (4) (b) (4)	26 Sep 2020 19:08:04

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:04:12

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:03:38
User entered 'other (OTHER)'	Elisa Moralez (b) (4) (b) (4)	26 Sep 2020 19:08:04

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:04:12

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:03:38
User entered 'every 3 months'	Elisa Moralez (b) (4) (b) (4)	26 Sep 2020 19:08:04

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:04:12

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:03:38
User entered 'Subcutaneous (SUBCUTANEOUS)'	Elisa Moralez (b) (4) (b) (4)	26 Sep 2020 19:08:04

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:04:12

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:03:38
User entered empty.	Elisa Moralez (b) (4) (b) (4)	26 Sep 2020 19:08:04

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:04:12

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:03:38
User entered 'un UNK 2014'	Elisa Moralez (b) (4) (b) (4)	26 Sep 2020 19:08:04

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:04:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:03:38
User entered '0'	Elisa Moralez (b) (4) (b) (4)	26 Sep 2020 19:08:04

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:04:12

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:03:38
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	26 Sep 2020 19:08:04

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:04:12

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:03:38
User entered empty.	Elisa Moralez (b) (4) (b) (4)	26 Sep 2020 19:08:04

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:04:12

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:03:38
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	26 Sep 2020 19:08:04

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:04:12

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Sep 2020 19:08:04

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:04:12

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Sep 2020 19:08:04

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:04:12

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Sep 2020 19:08:04

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:04:12

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: ANDROGENS, ATC: 3-OXOANDROSTEN (4) DERIVATIVES, PRODUCT: TESTOSTERONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Nov 2020 00:41:28
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Nov 2020 00:41:28
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:03:38
Data point term sent to Coder	System	02 Nov 2020 16:44:32
Coding entries removed.	Elisa Moralez (b) (4)	02 Nov 2020 16:44:12
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: ANDROGENS, ATC: 3-OXOANDROSTEN (4) DERIVATIVES, PRODUCT: TESTOSTERONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Sep 2020 04:35:37
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Sep 2020 04:35:37
Data point term sent to Coder	System	26 Sep 2020 19:10:55
User entered 'Testosterone Pellet'	Elisa Moralez (b) (4)	26 Sep 2020 19:10:39

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:04:12

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:03:38
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	26 Sep 2020 19:10:39

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:04:12

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User closed query 'Per DM CLR : Please note that Con Med indication should reflect a medical condition instead of what the drug does. Please review and update the Con Med indication with the corresponding AE or Med History eCRF so there is an appropriate match. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Nov 2020 19:38:11
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:03:38
Query 'Per DM CLR : Please note that Con Med indication should reflect a medical condition instead of what the drug does. Please review and update the Con Med indication with the corresponding AE or Med History eCRF so there is an appropriate match. ' answered with 'updated' (Site from DM).	Elisa Moralez (b) (4) (b) (4)	02 Nov 2020 16:44:22
User entered 'post menopausal' reason for change: New Information	Elisa Moralez (b) (4) (b) (4)	02 Nov 2020 16:44:12
User opened query 'Per DM CLR : Please note that Con Med indication should reflect a medical condition instead of what the drug does. Please review and update the Con Med indication with the corresponding AE or Med History eCRF so there is an appropriate match. ' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 10:51:21
User entered 'Hormone replacement therapy'	Elisa Moralez (b) (4) (b) (4)	26 Sep 2020 19:10:39

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:04:12

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:03:38
User entered '87.5'	Elisa Moralez (b) (4) (b) (4)	26 Sep 2020 19:10:39

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:04:12

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:03:38
User entered 'mg (mg)'	Elisa Moralez (b) (4) (b) (4)	26 Sep 2020 19:10:39

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:04:12

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:03:38
User entered empty.	Elisa Moralez (b) (4) (b) (4)	26 Sep 2020 19:10:39

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:04:12

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:03:38
User entered 'other (OTHER)'	Elisa Moralez (b) (4) (b) (4)	26 Sep 2020 19:10:39

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:04:12

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:03:38
User entered 'every 3 months'	Elisa Moralez (b) (4) (b) (4)	26 Sep 2020 19:10:39

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:04:12

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:03:38
User entered 'Subcutaneous (SUBCUTANEOUS)'	Elisa Moralez (b) (4) (b) (4)	26 Sep 2020 19:10:39

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:04:12

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:03:38
User entered empty.	Elisa Moralez (b) (4) (b) (4)	26 Sep 2020 19:10:39

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:04:12

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:03:38
User entered 'un UNK 2014'	Elisa Moralez (b) (4) (b) (4)	26 Sep 2020 19:10:39

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:04:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:03:38
User entered '0'	Elisa Moralez (b) (4) (b) (4)	26 Sep 2020 19:10:39

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:04:12

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:03:38
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	26 Sep 2020 19:10:39

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:04:12

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:03:38
User entered empty.	Elisa Moralez (b) (4) (b) (4)	26 Sep 2020 19:10:39

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:04:12

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:03:38
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	26 Sep 2020 19:10:39

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:04:12

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Sep 2020 19:10:39

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:04:12

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Sep 2020 19:10:39

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:04:12

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Sep 2020 19:10:39

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:04:12

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:58:52
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:03:38
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOIDS, PRODUCT: PREDNISOLONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Oct 2020 05:08:35
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Oct 2020 05:08:35
Data point term sent to Coder	System	21 Oct 2020 19:57:15
User entered 'Prednisolone'	Elisa Moralez (b) (4) (b) (4)	21 Oct 2020 19:56:25
DataPoint activated with code reason code Data required.	Elisa Moralez (b) (4) (b) (4)	21 Oct 2020 19:55:36
DataPoint inactivated with code reason code Data not required.	Elisa Moralez (b) (4) (b) (4)	26 Sep 2020 19:10:53

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:04:12

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:58:52
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:03:38
User entered 'No (N)'	Elisa Moralez (b) (4)	21 Oct 2020 19:56:25
DataPoint activated with code reason code Data required.	(b) (4) Elisa Moralez (b) (4)	21 Oct 2020 19:55:36
DataPoint inactivated with code reason code Data not required.	(b) (4) Elisa Moralez (b) (4)	26 Sep 2020 19:10:53

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:04:12

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:58:52
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:03:38
User entered 'Facial Swelling'	Elisa Moralez (b) (4)	21 Oct 2020 19:56:25
DataPoint activated with code reason code Data required.	(b) (4) Elisa Moralez (b) (4)	21 Oct 2020 19:55:36
DataPoint inactivated with code reason code Data not required.	(b) (4) Elisa Moralez (b) (4)	26 Sep 2020 19:10:53

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:04:12

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:58:52
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:03:38
User entered '25'	Elisa Moralez (b) (4)	21 Oct 2020 19:56:25
DataPoint activated with code reason code Data required.	(b) (4) Elisa Moralez (b) (4)	21 Oct 2020 19:55:36
DataPoint inactivated with code reason code Data not required.	(b) (4) Elisa Moralez (b) (4)	26 Sep 2020 19:10:53

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:04:12

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:58:52
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:03:38
User entered 'mg (mg)'	Elisa Moralez (b) (4)	21 Oct 2020 19:56:25
DataPoint activated with code reason code Data required.	(b) (4) Elisa Moralez (b) (4)	21 Oct 2020 19:55:36
DataPoint inactivated with code reason code Data not required.	(b) (4) Elisa Moralez (b) (4)	26 Sep 2020 19:10:53

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:04:12

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:58:52
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:03:38
User entered empty.	Elisa Moralez (b) (4)	21 Oct 2020 19:56:25
DataPoint activated with code reason code Data required.	(b) (4) Elisa Moralez (b) (4)	21 Oct 2020 19:55:36
DataPoint inactivated with code reason code Data not required.	(b) (4) Elisa Moralez (b) (4)	26 Sep 2020 19:10:53

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:04:12

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:58:52
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:03:38
User entered 'once daily (QD)'	Elisa Moralez (b) (4)	21 Oct 2020 19:56:25
DataPoint activated with code reason code Data required.	(b) (4) Elisa Moralez (b) (4)	21 Oct 2020 19:55:36
DataPoint inactivated with code reason code Data not required.	(b) (4) Elisa Moralez (b) (4)	26 Sep 2020 19:10:53

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:04:12

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:58:52
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:03:38
User entered empty.	Elisa Moralez (b) (4)	21 Oct 2020 19:56:25
DataPoint activated with code reason code Data required.	(b) (4) Elisa Moralez (b) (4)	21 Oct 2020 19:55:36
DataPoint inactivated with code reason code Data not required.	(b) (4) Elisa Moralez (b) (4)	26 Sep 2020 19:10:53

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:04:12

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:58:52
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:03:38
User entered 'Oral (ORAL)'	Elisa Moralez (b) (4)	21 Oct 2020 19:56:25
DataPoint activated with code reason code Data required.	(b) (4) Elisa Moralez (b) (4)	21 Oct 2020 19:55:36
DataPoint inactivated with code reason code Data not required.	(b) (4) Elisa Moralez (b) (4)	26 Sep 2020 19:10:53

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:04:12

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:58:52
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:03:38
User entered empty.	Elisa Moralez (b) (4)	21 Oct 2020 19:56:25
DataPoint activated with code reason code Data required.	(b) (4) Elisa Moralez (b) (4)	21 Oct 2020 19:55:36
DataPoint inactivated with code reason code Data not required.	(b) (4) Elisa Moralez (b) (4)	26 Sep 2020 19:10:53

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:04:12

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:58:52
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:03:38
User entered '17 Oct 2020'	Elisa Moralez (b) (4)	21 Oct 2020 19:56:25
DataPoint activated with code reason code Data required.	(b) (4) Elisa Moralez (b) (4)	21 Oct 2020 19:55:36
DataPoint inactivated with code reason code Data not required.	(b) (4) Elisa Moralez (b) (4)	26 Sep 2020 19:10:53

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:04:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:58:52
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:03:38
User entered '0'	Elisa Moralez (b) (4)	21 Oct 2020 19:56:25
DataPoint activated with code reason code Data required.	(b) (4) Elisa Moralez (b) (4)	21 Oct 2020 19:55:36
DataPoint inactivated with code reason code Data not required.	(b) (4) Elisa Moralez (b) (4)	26 Sep 2020 19:10:53

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:04:12

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:58:52
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:03:38
User entered 'No (N)'	Elisa Moralez (b) (4)	21 Oct 2020 19:56:25
DataPoint activated with code reason code Data required.	(b) (4) Elisa Moralez (b) (4)	21 Oct 2020 19:55:36
DataPoint inactivated with code reason code Data not required.	(b) (4) Elisa Moralez (b) (4)	26 Sep 2020 19:10:53

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:04:12

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:58:52
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:03:38
User entered '17 Oct 2020'	Elisa Moralez (b) (4)	21 Oct 2020 19:56:25
DataPoint activated with code reason code Data required.	(b) (4) Elisa Moralez (b) (4)	21 Oct 2020 19:55:36
DataPoint inactivated with code reason code Data not required.	(b) (4) Elisa Moralez (b) (4)	26 Sep 2020 19:10:53

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:04:12

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:58:52
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:03:38
User entered 'No (N)'	Elisa Moralez (b) (4)	21 Oct 2020 19:56:25
DataPoint activated with code reason code Data required.	(b) (4) Elisa Moralez (b) (4)	21 Oct 2020 19:55:36
DataPoint inactivated with code reason code Data not required.	(b) (4) Elisa Moralez (b) (4)	26 Sep 2020 19:10:53

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:04:12

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:58:52
User entered '1'	System	21 Oct 2020 19:56:25
DataPoint activated with code reason code Data required.	Elisa Moralez (b) (4)	21 Oct 2020 19:55:36
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Elisa Moralez (b) (4)	26 Sep 2020 19:10:53
	(b) (4)	

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:04:12

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:58:52
User entered '1'	System	21 Oct 2020 19:56:25
DataPoint activated with code reason code Data required.	Elisa Moralez (b) (4)	21 Oct 2020 19:55:36
DataPoint inactivated with code reason code Data not required.	Elisa Moralez (b) (4)	26 Sep 2020 19:10:53

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:04:12

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:58:52
User entered '804 (804)'	System	21 Oct 2020 19:56:25
DataPoint activated with code reason code Data required.	Elisa Moralez (b) (4)	21 Oct 2020 19:55:36
DataPoint inactivated with code reason code Data not required.	Elisa Moralez (b) (4)	26 Sep 2020 19:10:53

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:04:12

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:03:38
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: PREDNISOLONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Oct 2020 05:08:35
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Oct 2020 05:08:35
Data point term sent to Coder	System	21 Oct 2020 19:57:17
User entered 'Prednisolone'	Elisa Moralez (b) (4) (b) (4)	21 Oct 2020 19:56:48

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:04:12

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:03:38
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	21 Oct 2020 19:56:48

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:04:12

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:03:38
User entered 'Facial Swelling'	Elisa Moralez (b) (4) (b) (4)	21 Oct 2020 19:56:48

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:04:12

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:03:38
User entered '40'	Elisa Moralez (b) (4) (b) (4)	21 Oct 2020 19:56:48

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:04:12

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:03:38
User entered 'mg (mg)'	Elisa Moralez (b) (4) (b) (4)	21 Oct 2020 19:56:48

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:04:12

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:03:38
User entered empty.	Elisa Moralez (b) (4) (b) (4)	21 Oct 2020 19:56:48

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:04:12

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:03:38
User entered 'once daily (QD)'	Elisa Moralez (b) (4) (b) (4)	21 Oct 2020 19:56:48

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:04:12

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:03:38
User entered empty.	Elisa Moralez (b) (4) (b) (4)	21 Oct 2020 19:56:48

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:04:12

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:03:38
User entered 'Oral (ORAL)'	Elisa Moralez (b) (4) (b) (4)	21 Oct 2020 19:56:48

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:04:12

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:03:38
User entered empty.	Elisa Moralez (b) (4) (b) (4)	21 Oct 2020 19:56:48

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:04:12

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:03:38
User entered '18 Oct 2020'	Elisa Moralez (b) (4) (b) (4)	21 Oct 2020 19:56:48

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:04:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:03:38
User entered '0'	Elisa Moralez (b) (4) (b) (4)	21 Oct 2020 19:56:48

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:04:12

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:03:38
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	21 Oct 2020 19:56:48

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:04:12

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:03:38
User entered empty.	Elisa Moralez (b) (4) (b) (4)	21 Oct 2020 19:56:48

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:04:12

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:03:38
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	21 Oct 2020 19:56:48

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:04:12

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Oct 2020 19:56:48

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:04:12

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Oct 2020 19:56:48

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:04:12

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Oct 2020 19:56:48

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:04:12

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:58:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:03:38
User coded data point as ATC: DERMATOLOGICALS, ATC: OTHER DERMATOLOGICAL PREPARATIONS, ATC: OTHER DERMATOLOGICAL PREPARATIONS, ATC: OTHER DERMATOLOGICALS, PRODUCT: HYALURONIC ACID - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Oct 2020 04:52:31
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Oct 2020 04:52:31
Data point term sent to Coder	System	21 Oct 2020 19:58:23
User entered 'Voluma (crosslinked hyaluronic acid)'	Elisa Moralez (b) (4) (b) (4)	21 Oct 2020 19:57:22

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:04:12

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:58:58
DataPoint Verified.		05 Mar 2021 18:39:21
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Un-verified.	(b) (4)	
	Elisa Moralez (b) (4)	09 Dec 2020 21:05:19
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	Elisa Moralez (b) (4)	09 Dec 2020 21:05:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Nov 2020 22:03:38
User entered 'No (N)'	Elisa Moralez (b) (4)	21 Oct 2020 19:57:22
	(b) (4)	

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:04:12

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:58:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
User closed query 'Per DM CLR: Please note CM is used as a cosmetic procedure. Please ensure to Update PROPHYLAXIS FIELD to YES. Please update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Dec 2020 20:24:45
Query 'Per DM CLR: Please note CM is used as a cosmetic procedure. Please ensure to Update PROPHYLAXIS FIELD to YES. Please update as appropriate. ' answered with 'happy to, thank you' (Site from DM).	Elisa Moralez (b) (4) (b) (4)	09 Dec 2020 21:05:26
User opened query 'Per DM CLR: Please note CM is used as a cosmetic procedure. Please ensure to Update PROPHYLAXIS FIELD to YES. Please update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	09 Dec 2020 08:21:18
DataPoint Verified.		02 Nov 2020 22:03:38
User entered 'Cosmetic Procedure'	Elisa Moralez (b) (4) (b) (4)	21 Oct 2020 19:57:22

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:04:12

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:58:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:03:38
User entered 'l'	Elisa Moralez (b) (4) (b) (4)	21 Oct 2020 19:57:22

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:04:12

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:58:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:03:38
User entered 'mL (mL)'	Elisa Moralez (b) (4) (b) (4)	21 Oct 2020 19:57:22

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:04:12

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:58:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:03:38
User entered empty.	Elisa Moralez (b) (4) (b) (4)	21 Oct 2020 19:57:22

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:04:12

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:58:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:03:38
User entered 'once daily (QD)'	Elisa Moralez (b) (4) (b) (4)	21 Oct 2020 19:57:22

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:04:12

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:58:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:03:38
User entered empty.	Elisa Moralez (b) (4) (b) (4)	21 Oct 2020 19:57:22

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:04:12

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:58:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:03:38
User entered 'Subcutaneous (SUBCUTANEOUS)'	Elisa Moralez (b) (4) (b) (4)	21 Oct 2020 19:57:22

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:04:12

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:58:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:03:38
User entered empty.	Elisa Moralez (b) (4) (b) (4)	21 Oct 2020 19:57:22

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:04:12

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:58:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:03:38
User entered '02 Oct 2020'	Elisa Moralez (b) (4) (b) (4)	21 Oct 2020 19:57:22

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:04:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:58:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:03:38
User entered '0'	Elisa Moralez (b) (4) (b) (4)	21 Oct 2020 19:57:22

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:04:12

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:58:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:03:38
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	21 Oct 2020 19:57:22

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:04:12

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:58:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:03:38
User entered '02 Oct 2020'	Elisa Moralez (b) (4) (b) (4)	21 Oct 2020 19:57:22

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:04:12

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:58:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:03:38
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	21 Oct 2020 19:57:22

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:04:12

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:58:58
User entered '1'	System	21 Oct 2020 19:57:22

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:04:12

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:58:58
User entered '1'	System	21 Oct 2020 19:57:22

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:04:12

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:58:58
User entered '804 (804)'	System	21 Oct 2020 19:57:22

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:04:12

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:59:03
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:08:27
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: NAPROXEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Mar 2021 13:49:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Mar 2021 13:49:45
Data point term sent to Coder	System	11 Mar 2021 15:58:18
Coding entries removed.	Elisa Moralez (b) (4)	11 Mar 2021 15:57:27
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 22:31:37
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: NAPROXEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Mar 2021 20:12:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Mar 2021 20:12:45
Data point term sent to Coder	System	03 Mar 2021 20:11:36
User entered 'naproxen'	Elisa Moralez (b) (4)	03 Mar 2021 20:11:31

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:04:12

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:59:03
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:08:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 22:31:37
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	03 Mar 2021 20:11:31

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:04:12

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:59:03
DataPoint Verified.	Heather Davis (b) (4)	08 Apr 2021 18:11:31
User signature succeeded.	(b) (4)	
	Veronica Fragoso (b) (4)	24 Mar 2021 22:08:27
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria. ' (Site from DM).	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 19:54:48
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria. ' answered with 'AEs have been updated, thank you' (Site from DM).	Elisa Moralez (b) (4)	23 Mar 2021 19:17:44
	(b) (4)	

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:04:12

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria. ' (Site from DM). DataPoint Un-verified.	(b) (4), (b) (6) (b) (4)	21 Mar 2021 02:07:25
	Elisa Moralez (b) (4) (b) (4)	11 Mar 2021 15:57:27
User entered 'Headache, Left arm injection site swelling' reason for change: Data Entry Error DataPoint Verified.	Elisa Moralez (b) (4) (b) (4) (b) (4), (b) (6)	11 Mar 2021 15:57:27 03 Mar 2021 22:31:37
User entered 'headache'	Elisa Moralez (b) (4) (b) (4)	03 Mar 2021 20:11:31

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:04:12

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:59:03
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:08:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 22:31:37
User entered '220'	Elisa Moralez (b) (4) (b) (4)	03 Mar 2021 20:11:31

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:04:12

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:59:03
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:08:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 22:31:37
User entered 'mg (mg)'	Elisa Moralez (b) (4) (b) (4)	03 Mar 2021 20:11:31

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:04:12

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:59:03
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:08:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 22:31:37
User entered empty.	Elisa Moralez (b) (4) (b) (4)	03 Mar 2021 20:11:31

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:04:12

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:59:03
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:08:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 22:31:37
User entered 'once (ONCE)'	Elisa Moralez (b) (4) (b) (4)	03 Mar 2021 20:11:31

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:04:12

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:59:03
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:08:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 22:31:37
User entered empty.	Elisa Moralez (b) (4) (b) (4)	03 Mar 2021 20:11:31

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:04:12

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:59:03
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:08:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 22:31:37
User entered 'Oral (ORAL)'	Elisa Moralez (b) (4) (b) (4)	03 Mar 2021 20:11:31

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:04:12

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:59:03
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:08:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 22:31:37
User entered empty.	Elisa Moralez (b) (4) (b) (4)	03 Mar 2021 20:11:31

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:04:12

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:59:03
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:08:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 22:31:37
User entered '16 Oct 2020'	Elisa Moralez (b) (4) (b) (4)	03 Mar 2021 20:11:31

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:04:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:59:03
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:08:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 22:31:37
User entered '0'	Elisa Moralez (b) (4) (b) (4)	03 Mar 2021 20:11:31

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:04:12

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:59:03
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:08:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 22:31:37
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	03 Mar 2021 20:11:31

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:04:12

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:59:03
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:08:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 22:31:37
User entered '16 Oct 2020'	Elisa Moralez (b) (4) (b) (4)	03 Mar 2021 20:11:31

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:04:12

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:59:03
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:08:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 22:31:37
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	03 Mar 2021 20:11:31

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:04:12

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:59:03
User entered empty.	System	03 Mar 2021 20:11:31

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:04:12

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:59:03
User entered empty.	System	03 Mar 2021 20:11:31

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:04:12

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:59:03
User entered empty.	System	03 Mar 2021 20:11:31

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:04:12

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:59:06
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:08:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 03:03:55
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) (b) (4)	10 Mar 2021 10:50:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Mar 2021 10:50:50
Data point term sent to Coder	System	09 Mar 2021 21:57:01
User entered 'Amoxicillin / Clavulanic acid'	Elisa Moralez (b) (4) (b) (4)	09 Mar 2021 21:56:39

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:04:12

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:59:06
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:08:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 03:03:55
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	09 Mar 2021 21:56:39

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:04:12

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:59:06
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:08:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 03:03:55
User entered 'Facial swelling'	Elisa Moralez (b) (4) (b) (4)	09 Mar 2021 21:56:39

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:04:12

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:59:06
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:08:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 03:03:55
User entered '875/125'	Elisa Moralez (b) (4) (b) (4)	09 Mar 2021 21:56:39

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:04:12

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:59:06
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:08:27
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 03:03:55
User entered 'mg (mg)'	Elisa Moralez (b) (4)	09 Mar 2021 21:56:39

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:04:12

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:59:06
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:08:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 03:03:55
User entered empty.	Elisa Moralez (b) (4) (b) (4)	09 Mar 2021 21:56:39

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:04:12

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:59:06
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:08:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 03:03:55
User entered 'twice daily (BID)'	Elisa Moralez (b) (4) (b) (4)	09 Mar 2021 21:56:39

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:04:12

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:59:06
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:08:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 03:03:55
User entered empty.	Elisa Moralez (b) (4) (b) (4)	09 Mar 2021 21:56:39

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:04:12

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:59:06
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:08:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 03:03:55
User entered 'Oral (ORAL)'	Elisa Moralez (b) (4) (b) (4)	09 Mar 2021 21:56:39

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:04:12

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:59:06
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:08:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 03:03:55
User entered empty.	Elisa Moralez (b) (4) (b) (4)	09 Mar 2021 21:56:39

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:04:12

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:59:06
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:08:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 03:03:55
User entered '17 Oct 2020'	Elisa Moralez (b) (4) (b) (4)	09 Mar 2021 21:56:39

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:04:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:59:06
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:08:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 03:03:55
User entered '0'	Elisa Moralez (b) (4) (b) (4)	09 Mar 2021 21:56:39

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:04:12

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:59:06
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:08:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 03:03:55
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	09 Mar 2021 21:56:39

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:04:12

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:59:06
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:08:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 03:03:55
User entered '21 Nov 2020'	Elisa Moralez (b) (4) (b) (4)	09 Mar 2021 21:56:39

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:04:12

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:59:06
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:08:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 03:03:55
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	09 Mar 2021 21:56:39

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:04:12

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:59:06
User entered '2'	System	09 Mar 2021 21:56:39

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:04:12

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:59:06
User entered '1'	System	09 Mar 2021 21:56:39

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:04:12

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:59:06
User entered '804 (804)'	System	09 Mar 2021 21:56:39

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:04:12

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:59:09
DataPoint Verified.	Heather Davis (b) (4)	08 Apr 2021 18:11:31
User signature succeeded.	(b) (4) Veronica Fragoso (b) (4)	24 Mar 2021 22:08:27
User coded data point as ATC: DERMATOLOGICALS, ATC: OTHER DERMATOLOGICAL PREPARATIONS, ATC: OTHER DERMATOLOGICAL PREPARATIONS, ATC: OTHER DERMATOLOGICALS, PRODUCT: BOTULINUM TOXIN TYPE A, PRODUCTSYNONYM: BOTOX - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	10 Mar 2021 11:17:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Mar 2021 11:17:50
Data point term sent to Coder	System	09 Mar 2021 21:58:02
User entered 'Botulinum Toxin (Botox)'	Elisa Moralez (b) (4) (b) (4)	09 Mar 2021 21:57:23

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:04:12

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:59:09
DataPoint Verified.	Heather Davis (b) (4)	08 Apr 2021 18:11:31
User signature succeeded.	(b) (4) Veronica Fragoso (b) (4)	24 Mar 2021 22:08:27
User entered 'Yes (Y)'	(b) (4) Elisa Moralez (b) (4)	09 Mar 2021 21:57:23

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:04:12

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:59:09
DataPoint Verified.	Heather Davis (b) (4)	08 Apr 2021 18:11:31
User signature succeeded.	(b) (4) Veronica Fragoso (b) (4)	24 Mar 2021 22:08:27
User entered 'Facial cosmetic injection(wrinkles)'	(b) (4) Elisa Moralez (b) (4)	09 Mar 2021 21:57:23

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:04:12

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:59:09
DataPoint Verified.	Heather Davis (b) (4)	08 Apr 2021 18:11:31
User signature succeeded.	(b) (4) Veronica Fragoso (b) (4)	24 Mar 2021 22:08:27
User entered 'I'	(b) (4) Elisa Moralez (b) (4)	09 Mar 2021 21:57:23
	(b) (4)	

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:04:12

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:59:09
DataPoint Verified.	Heather Davis (b) (4)	08 Apr 2021 18:11:31
User signature succeeded.	(b) (4) Veronica Fragoso (b) (4)	24 Mar 2021 22:08:27
User entered 'Other (OTHER)'	(b) (4) Elisa Moralez (b) (4)	09 Mar 2021 21:57:23

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:04:12

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:59:09
DataPoint Verified.	Heather Davis (b) (4)	08 Apr 2021 18:11:31
User signature succeeded.	(b) (4) Veronica Fragoso (b) (4)	24 Mar 2021 22:08:27
User entered 'injection'	(b) (4) Elisa Moralez (b) (4)	09 Mar 2021 21:57:23

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:04:12

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:59:09
DataPoint Verified.	Heather Davis (b) (4)	08 Apr 2021 18:11:31
User signature succeeded.	(b) (4) Veronica Fragoso (b) (4)	24 Mar 2021 22:08:27
User entered 'once (ONCE)'	(b) (4) Elisa Moralez (b) (4)	09 Mar 2021 21:57:23

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:04:12

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:59:09
DataPoint Verified.	Heather Davis (b) (4)	08 Apr 2021 18:11:31
User signature succeeded.	(b) (4) Veronica Fragoso (b) (4)	24 Mar 2021 22:08:27
User entered empty.	(b) (4) Elisa Moralez (b) (4)	09 Mar 2021 21:57:23
	(b) (4)	

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:04:12

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:59:09
DataPoint Verified.	Heather Davis (b) (4)	08 Apr 2021 18:11:31
User signature succeeded.	(b) (4) Veronica Fragoso (b) (4)	24 Mar 2021 22:08:27
User entered 'Subcutaneous (SUBCUTANEOUS)'	(b) (4) Elisa Moralez (b) (4)	09 Mar 2021 21:57:23

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:04:12

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:59:09
DataPoint Verified.	Heather Davis (b) (4)	08 Apr 2021 18:11:31
User signature succeeded.	(b) (4) Veronica Fragoso (b) (4)	24 Mar 2021 22:08:27
User entered empty.	(b) (4) Elisa Moralez (b) (4)	09 Mar 2021 21:57:23
	(b) (4)	

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:04:12

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:59:09
DataPoint Verified.	Heather Davis (b) (4)	08 Apr 2021 18:11:31
User signature succeeded.	(b) (4) Veronica Fragoso (b) (4)	24 Mar 2021 22:08:27
User entered 'un Oct 2020'	(b) (4) Elisa Moralez (b) (4)	09 Mar 2021 21:57:23

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:04:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:59:09
DataPoint Verified.	Heather Davis (b) (4)	08 Apr 2021 18:11:31
User signature succeeded.	(b) (4) Veronica Fragoso (b) (4)	24 Mar 2021 22:08:27
User entered '0'	(b) (4) Elisa Moralez (b) (4)	09 Mar 2021 21:57:23
	(b) (4)	

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:04:12

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:59:09
DataPoint Verified.	Heather Davis (b) (4)	08 Apr 2021 18:11:31
User signature succeeded.	(b) (4) Veronica Fragoso (b) (4)	24 Mar 2021 22:08:27
User entered 'No (N)'	(b) (4) Elisa Moralez (b) (4)	09 Mar 2021 21:57:23

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:04:12

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:59:09
DataPoint Verified.	Heather Davis (b) (4)	08 Apr 2021 18:11:31
User signature succeeded.	(b) (4) Veronica Fragoso (b) (4)	24 Mar 2021 22:08:27
User entered 'un Oct 2020'	(b) (4) Elisa Moralez (b) (4)	09 Mar 2021 21:57:23

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:04:12

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:59:09
DataPoint Verified.	Heather Davis (b) (4)	08 Apr 2021 18:11:31
User signature succeeded.	(b) (4) Veronica Fragoso (b) (4)	24 Mar 2021 22:08:27
User entered 'No (N)'	(b) (4) Elisa Moralez (b) (4)	09 Mar 2021 21:57:23

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:04:12

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:59:09
User entered empty.	System	09 Mar 2021 21:57:23

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:04:12

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:59:09
User entered empty.	System	09 Mar 2021 21:57:23

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:04:12

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:59:09
User entered empty.	System	09 Mar 2021 21:57:23

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:04:12

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:59:13
DataPoint Verified.	Heather Davis (b) (4)	08 Apr 2021 18:11:31
User signature succeeded.	(b) (4) Veronica Fragoso (b) (4)	24 Mar 2021 22:08:27
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	09 Mar 2021 21:59:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	09 Mar 2021 21:59:40
Data point term sent to Coder	System	09 Mar 2021 21:59:03
User entered 'Influenza Vaccine'	Elisa Moralez (b) (4) (b) (4)	09 Mar 2021 21:58:11

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:04:12

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:59:13
DataPoint Verified.	Heather Davis (b) (4)	08 Apr 2021 18:11:31
User signature succeeded.	(b) (4) Veronica Fragoso (b) (4)	24 Mar 2021 22:08:27
User entered 'Yes (Y)'	(b) (4) Elisa Moralez (b) (4)	09 Mar 2021 21:58:11

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:04:12

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:59:13
DataPoint Verified.	Heather Davis (b) (4)	08 Apr 2021 18:11:31
User signature succeeded.	(b) (4) Veronica Fragoso (b) (4)	24 Mar 2021 22:08:27
User entered 'preventative healthcare'	(b) (4) Elisa Moralez (b) (4)	09 Mar 2021 21:58:11

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:04:12

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:59:13
DataPoint Verified.	Heather Davis (b) (4)	08 Apr 2021 18:11:31
User signature succeeded.	(b) (4) Veronica Fragoso (b) (4)	24 Mar 2021 22:08:27
User entered 'I'	(b) (4) Elisa Moralez (b) (4)	09 Mar 2021 21:58:11

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:04:12

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:59:13
DataPoint Verified.	Heather Davis (b) (4)	08 Apr 2021 18:11:31
User signature succeeded.	(b) (4) Veronica Fragoso (b) (4)	24 Mar 2021 22:08:27
User entered 'Other (OTHER)'	(b) (4) Elisa Moralez (b) (4)	09 Mar 2021 21:58:11

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:04:12

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:59:13
DataPoint Verified.	Heather Davis (b) (4)	08 Apr 2021 18:11:31
User signature succeeded.	(b) (4) Veronica Fragoso (b) (4)	24 Mar 2021 22:08:27
User entered 'injection'	(b) (4) Elisa Moralez (b) (4)	09 Mar 2021 21:58:11

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:04:12

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:59:13
DataPoint Verified.	Heather Davis (b) (4)	08 Apr 2021 18:11:31
User signature succeeded.	(b) (4) Veronica Fragoso (b) (4)	24 Mar 2021 22:08:27
User entered 'once (ONCE)'	(b) (4) Elisa Moralez (b) (4)	09 Mar 2021 21:58:11

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:04:12

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:59:13
DataPoint Verified.	Heather Davis (b) (4)	08 Apr 2021 18:11:31
User signature succeeded.	(b) (4) Veronica Fragoso (b) (4)	24 Mar 2021 22:08:27
User entered empty.	(b) (4) Elisa Moralez (b) (4)	09 Mar 2021 21:58:11
	(b) (4)	

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:04:12

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:59:13
DataPoint Verified.	Heather Davis (b) (4)	08 Apr 2021 18:11:31
User signature succeeded.	(b) (4) Veronica Fragoso (b) (4)	24 Mar 2021 22:08:27
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) Elisa Moralez (b) (4)	09 Mar 2021 21:58:11

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:04:12

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:59:13
DataPoint Verified.	Heather Davis (b) (4)	08 Apr 2021 18:11:31
User signature succeeded.	(b) (4) Veronica Fragoso (b) (4)	24 Mar 2021 22:08:27
User entered empty.	(b) (4) Elisa Moralez (b) (4)	09 Mar 2021 21:58:11
	(b) (4)	

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:04:12

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:59:13
DataPoint Verified.	Heather Davis (b) (4)	08 Apr 2021 18:11:31
User signature succeeded.	(b) (4) Veronica Fragoso (b) (4)	24 Mar 2021 22:08:27
User entered '23 Nov 2020'	(b) (4) Elisa Moralez (b) (4)	09 Mar 2021 21:58:11

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:04:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:59:13
DataPoint Verified.	Heather Davis (b) (4)	08 Apr 2021 18:11:31
User signature succeeded.	(b) (4) Veronica Fragoso (b) (4)	24 Mar 2021 22:08:27
User entered '0'	(b) (4) Elisa Moralez (b) (4)	09 Mar 2021 21:58:11

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:04:12

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:59:13
DataPoint Verified.	Heather Davis (b) (4)	08 Apr 2021 18:11:31
User signature succeeded.	(b) (4) Veronica Fragoso (b) (4)	24 Mar 2021 22:08:27
User entered 'No (N)'	(b) (4) Elisa Moralez (b) (4)	09 Mar 2021 21:58:11

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:04:12

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:59:13
DataPoint Verified.	Heather Davis (b) (4)	08 Apr 2021 18:11:31
User signature succeeded.	(b) (4) Veronica Fragoso (b) (4)	24 Mar 2021 22:08:27
User entered '23 Nov 2020'	(b) (4) Elisa Moralez (b) (4)	09 Mar 2021 21:58:11

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:04:12

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:59:13
DataPoint Verified.	Heather Davis (b) (4)	08 Apr 2021 18:11:31
User signature succeeded.	(b) (4) Veronica Fragoso (b) (4)	24 Mar 2021 22:08:27
User entered 'No (N)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	09 Mar 2021 21:58:11

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:04:12

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:59:13
User entered empty.	System	09 Mar 2021 21:58:11

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:04:12

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:59:13
User entered empty.	System	09 Mar 2021 21:58:11

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:04:12

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:59:13
User entered empty.	System	09 Mar 2021 21:58:11

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:04:12

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:08:34
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: NAPROXEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Apr 2021 20:30:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Apr 2021 20:30:40
Data point term sent to Coder	System	19 Apr 2021 20:29:21
User entered 'Naproxen'	Elisa Morales (b) (4) (b) (4)	19 Apr 2021 20:28:21

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:04:12

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:08:34
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	19 Apr 2021 20:28:21

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:04:12

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:08:34
User entered 'Upper Respiratory Infection'	Elisa Moralez (b) (4) (b) (4)	19 Apr 2021 20:28:21

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:04:12

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:08:34
User entered '500'	Elisa Moralez (b) (4) (b) (4)	19 Apr 2021 20:28:21

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:04:12

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:08:34
User entered 'mg (mg)'	Elisa Moralez (b) (4) (b) (4)	19 Apr 2021 20:28:21

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:04:12

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:08:34
User entered empty.	Elisa Moralez (b) (4) (b) (4)	19 Apr 2021 20:28:21

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:04:12

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:08:34
User entered 'three times daily (TID)'	Elisa Moralez (b) (4) (b) (4)	19 Apr 2021 20:28:21

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:04:12

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:08:34
User entered empty.	Elisa Moralez (b) (4) (b) (4)	19 Apr 2021 20:28:21

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:04:12

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:08:34
User entered 'Oral (ORAL)'	Elisa Moralez (b) (4) (b) (4)	19 Apr 2021 20:28:21

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:04:12

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:08:34
User entered empty.	Elisa Moralez (b) (4) (b) (4)	19 Apr 2021 20:28:21

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:04:12

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:08:34
User entered '29 Mar 2021'	Elisa Moralez (b) (4) (b) (4)	19 Apr 2021 20:28:21

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:04:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:08:34
User entered '0'	Elisa Moralez (b) (4) (b) (4)	19 Apr 2021 20:28:21

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:04:12

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:08:34
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	19 Apr 2021 20:28:21

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:04:12

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:08:34
User entered '01 Apr 2021'	Elisa Moralez (b) (4) (b) (4)	19 Apr 2021 20:28:21

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:04:12

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:08:34
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	19 Apr 2021 20:28:21

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:04:12

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	19 Apr 2021 20:28:21

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:04:12

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Apr 2021 20:28:21

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:04:12

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Apr 2021 20:28:21

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:04:12

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:08:28
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: THIRD-GENERATION CEPHALOSPORINS, PRODUCT: CEFDINIR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Apr 2021 20:30:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Apr 2021 20:30:40
Data point term sent to Coder	System	19 Apr 2021 20:29:22
User entered 'Cefdinir'	Elisa Moralez (b) (4) (b) (4)	19 Apr 2021 20:28:40

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:04:12

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:08:28
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	19 Apr 2021 20:28:40

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:04:12

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:08:28
User entered 'Upper Respiratory Infection'	Elisa Moralez (b) (4) (b) (4)	19 Apr 2021 20:28:40

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:04:12

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:08:28
User entered '300'	Elisa Moralez (b) (4) (b) (4)	19 Apr 2021 20:28:40

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:04:12

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:08:28
User entered 'mg (mg)'	Elisa Moralez (b) (4) (b) (4)	19 Apr 2021 20:28:40

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:04:12

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:08:28
User entered empty.	Elisa Moralez (b) (4) (b) (4)	19 Apr 2021 20:28:40

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:04:12

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:08:28
User entered 'twice daily (BID)'	Elisa Moralez (b) (4) (b) (4)	19 Apr 2021 20:28:40

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:04:12

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:08:28
User entered empty.	Elisa Moralez (b) (4) (b) (4)	19 Apr 2021 20:28:40

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:04:12

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:08:28
User entered 'Oral (ORAL)'	Elisa Moralez (b) (4) (b) (4)	19 Apr 2021 20:28:40

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:04:12

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:08:28
User entered empty.	Elisa Moralez (b) (4) (b) (4)	19 Apr 2021 20:28:40

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:04:12

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:08:28
User entered '30 Mar 2021'	Elisa Moralez (b) (4) (b) (4)	19 Apr 2021 20:28:40

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:04:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:08:28
User entered '0'	Elisa Moralez (b) (4) (b) (4)	19 Apr 2021 20:28:40

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:04:12

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:34:31
DataPoint Un-verified.	Elisa Moralez (b) (4) (b) (4)	21 Apr 2021 18:00:00
User entered 'No (N)' reason for change: Data Entry Error	Elisa Moralez (b) (4) (b) (4)	21 Apr 2021 18:00:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:08:28
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	19 Apr 2021 20:28:40

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:04:12

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:34:31
DataPoint Un-verified.	Elisa Moralez (b) (4) (b) (4)	21 Apr 2021 18:00:00
User entered '08 Apr 2021' reason for change: Data Entry Error	Elisa Moralez (b) (4) (b) (4)	21 Apr 2021 18:00:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:08:28
User entered empty.	Elisa Moralez (b) (4) (b) (4)	19 Apr 2021 20:28:40

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:04:12

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:08:28
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	19 Apr 2021 20:28:40

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:04:12

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	19 Apr 2021 20:28:40

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:04:12

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Apr 2021 20:28:40

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:04:12

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Apr 2021 20:28:40

US3322329

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 17:04:12

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:32:30
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 15:28:36
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	21 Oct 2020 19:57:33

US3322329

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:04:12

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 15:28:43
User entered '02 Oct 2020'	Elisa Moralez (b) (4) (b) (4)	21 Oct 2020 19:57:57

US3322329

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:04:12

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 15:28:43
User entered 'Dermal filler injection'	Elisa Moralez (b) (4) (b) (4)	21 Oct 2020 19:57:57

US3322329

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:04:12

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 15:28:43
User entered 'Other (OTHER)'	Elisa Moralez (b) (4) (b) (4)	21 Oct 2020 19:57:57

US3322329

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:04:12

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 15:28:43
User entered 'cosmetic'	Elisa Moralez (b) (4) (b) (4)	21 Oct 2020 19:57:57

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:12

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.		22 Oct 2020 18:43:23
User entered 'USA-US060-2020-MRNA-1273-P301000006'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:12

Serious

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.		22 Oct 2020 18:43:23
User entered 'Yes (Y)'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:12

Death

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.		22 Oct 2020 18:43:23
User entered 'No (N)'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:12

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.		22 Oct 2020 18:43:23
User entered 'No (N)'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:12

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.		22 Oct 2020 18:43:23
User entered 'No (N)'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:12

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.		22 Oct 2020 18:43:23
User entered 'No (N)'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:12

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.		22 Oct 2020 18:43:23
User entered 'No (N)'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:12

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.		22 Oct 2020 18:43:23
User entered 'Yes (Y)'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:12

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.		22 Oct 2020 18:43:23
User entered 'Veronica'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:12

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.		22 Oct 2020 18:43:23
User entered 'Fragoso'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:12

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.		22 Oct 2020 18:43:23
User entered '6550 Mapleridge Street'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:12

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.		22 Oct 2020 18:43:23
User entered 'Houston'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:12

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.		22 Oct 2020 18:43:23
User entered 'TX'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:12

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.		22 Oct 2020 18:43:23
User entered '77081'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:12

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:14:51
DataPoint Verified.		02 Nov 2020 22:06:48
User entered 'US'	System	22 Oct 2020 18:43:30

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:12

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
	(b) (4)	
User entered '5'	System	16 Nov 2020 14:17:45
User entered '4'	System	09 Nov 2020 15:40:20
User entered '3'	System	03 Nov 2020 15:39:15
User entered '2'	System	02 Nov 2020 22:15:06
User entered '1'	System	22 Oct 2020 18:43:30

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:12

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.		22 Oct 2020 18:43:23
User entered 'USA-US060-2020-MRNA-1273-P301000006'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:12

Serious

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.		22 Oct 2020 18:43:23
User entered 'Yes (Y)'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:12

Death

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.		22 Oct 2020 18:43:23
User entered 'No (N)'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:12

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.		22 Oct 2020 18:43:23
User entered 'No (N)'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:12

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.		22 Oct 2020 18:43:23
User entered 'No (N)'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:12

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.		22 Oct 2020 18:43:23
User entered 'No (N)'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:12

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.		22 Oct 2020 18:43:23
User entered 'No (N)'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:12

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.		22 Oct 2020 18:43:23
User entered 'Yes (Y)'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:12

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.		22 Oct 2020 18:43:23
User entered 'Veronica'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:12

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.		22 Oct 2020 18:43:23
User entered 'Fragoso'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:12

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.		22 Oct 2020 18:43:23
User entered '6550 Mapleridge Street'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:12

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (v) (+), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.		22 Oct 2020 18:43:23
User entered 'Houston'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:12

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.		22 Oct 2020 18:43:23
User entered 'TX'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:12

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.		22 Oct 2020 18:43:23
User entered '77081'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:12

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:14:51
DataPoint Verified.		02 Nov 2020 22:06:48
User entered 'US'	System	22 Oct 2020 18:43:30

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:12

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
	(b) (4)	
User entered '5'	System	16 Nov 2020 14:17:45
User entered '4'	System	09 Nov 2020 15:40:20
User entered '3'	System	03 Nov 2020 15:39:15
User entered '2'	System	02 Nov 2020 22:15:06
User entered '1'	System	22 Oct 2020 18:43:30

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:04:12

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:06:48
User entered '22/Oct/2020 18:43'	System	22 Oct 2020 18:43:30

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:04:12

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:14:51
DataPoint Verified.		02 Nov 2020 22:06:48
User entered 'I'		22 Oct 2020 18:43:30

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:12

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.		22 Oct 2020 18:43:23
User entered 'USA-US060-2020-MRNA-1273-P301000006'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:12

Serious

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.		22 Oct 2020 18:43:23
User entered 'Yes (Y)'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:12

Death

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.		22 Oct 2020 18:43:23
User entered 'No (N)'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:12

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.		22 Oct 2020 18:43:23
User entered 'No (N)'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:12

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.		22 Oct 2020 18:43:23
User entered 'No (N)'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:12

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.		22 Oct 2020 18:43:23
User entered 'No (N)'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:12

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.		22 Oct 2020 18:43:23
User entered 'No (N)'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:12

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.		22 Oct 2020 18:43:23
User entered 'Yes (Y)'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:12

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.		22 Oct 2020 18:43:23
User entered 'Veronica'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:12

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.		22 Oct 2020 18:43:23
User entered 'Fragoso'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:12

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.		22 Oct 2020 18:43:23
User entered '6550 Mapleridge Street'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:12

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.		22 Oct 2020 18:43:23
User entered 'Houston'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:12

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.		22 Oct 2020 18:43:23
User entered 'TX'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:12

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.		22 Oct 2020 18:43:23
User entered '77081'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:12

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
Reviewed for Safety.	(b) (4) (d) (4), (b) (6)	02 Nov 2020 22:14:51
DataPoint Verified.		02 Nov 2020 22:06:48
User entered 'US'	System	22 Oct 2020 18:43:30

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:12

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
	(b) (4)	
User entered '5'	System	16 Nov 2020 14:17:45
User entered '4'	System	09 Nov 2020 15:40:20
User entered '3'	System	03 Nov 2020 15:39:15
User entered '2'	System	02 Nov 2020 22:15:06
User entered '1'	System	22 Oct 2020 18:43:30

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:04:12

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 21:03:14
User entered '02/Nov/2020 22:15'	System	02 Nov 2020 22:15:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:04:12

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 21:03:14
Reviewed for Safety.		03 Nov 2020 15:39:03
User entered 'I'		02 Nov 2020 22:15:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:12

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.		22 Oct 2020 18:43:23
User entered 'USA-US060-2020-MRNA-1273-P301000006'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:12

Serious

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.		22 Oct 2020 18:43:23
User entered 'Yes (Y)'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:12

Death

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (D) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.		22 Oct 2020 18:43:23
User entered 'No (N)'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:12

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.		22 Oct 2020 18:43:23
User entered 'No (N)'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:12

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.		22 Oct 2020 18:43:23
User entered 'No (N)'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:12

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.		22 Oct 2020 18:43:23
User entered 'No (N)'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:12

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.		22 Oct 2020 18:43:23
User entered 'No (N)'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:12

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.		22 Oct 2020 18:43:23
User entered 'Yes (Y)'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:12

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.		22 Oct 2020 18:43:23
User entered 'Veronica'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:12

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.		22 Oct 2020 18:43:23
User entered 'Fragoso'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:12

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.		22 Oct 2020 18:43:23
User entered '6550 Mapleridge Street'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:12

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.		22 Oct 2020 18:43:23
User entered 'Houston'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:12

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.		22 Oct 2020 18:43:23
User entered 'TX'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:12

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.		22 Oct 2020 18:43:23
User entered '77081'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:12

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
Reviewed for Safety.	(b) (4) (D) (4), (b) (6)	02 Nov 2020 22:14:51
DataPoint Verified.		02 Nov 2020 22:06:48
User entered 'US'	System	22 Oct 2020 18:43:30

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:12

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
	(b) (4)	
User entered '5'	System	16 Nov 2020 14:17:45
User entered '4'	System	09 Nov 2020 15:40:20
User entered '3'	System	03 Nov 2020 15:39:15
User entered '2'	System	02 Nov 2020 22:15:06
User entered '1'	System	22 Oct 2020 18:43:30

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:04:12

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 21:03:14
User entered '03/Nov/2020 15:39'	System	03 Nov 2020 15:39:15

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:04:12

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 21:03:14
Reviewed for Safety.		03 Nov 2020 15:40:42
User entered 'I'		03 Nov 2020 15:39:15

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:12

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.		22 Oct 2020 18:43:23
User entered 'USA-US060-2020-MRNA-1273-P301000006'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:12

Serious

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.		22 Oct 2020 18:43:23
User entered 'Yes (Y)'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:12

Death

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.		22 Oct 2020 18:43:23
User entered 'No (N)'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:12

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.		22 Oct 2020 18:43:23
User entered 'No (N)'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:12

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.		22 Oct 2020 18:43:23
User entered 'No (N)'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:12

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.		22 Oct 2020 18:43:23
User entered 'No (N)'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:12

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.		22 Oct 2020 18:43:23
User entered 'No (N)'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:12

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.		22 Oct 2020 18:43:23
User entered 'Yes (Y)'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:12

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.		22 Oct 2020 18:43:23
User entered 'Veronica'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:12

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.		22 Oct 2020 18:43:23
User entered 'Fragoso'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:12

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.		22 Oct 2020 18:43:23
User entered '6550 Mapleridge Street'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:12

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.		22 Oct 2020 18:43:23
User entered 'Houston'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:12

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.		22 Oct 2020 18:43:23
User entered 'TX'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:12

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.		22 Oct 2020 18:43:23
User entered '77081'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:12

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:14:51
DataPoint Verified.		02 Nov 2020 22:06:48
User entered 'US'	System	22 Oct 2020 18:43:30

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:12

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
	(b) (4)	
User entered '5'	System	16 Nov 2020 14:17:45
User entered '4'	System	09 Nov 2020 15:40:20
User entered '3'	System	03 Nov 2020 15:39:15
User entered '2'	System	02 Nov 2020 22:15:06
User entered '1'	System	22 Oct 2020 18:43:30

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:04:12

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 21:03:14
User entered '09/Nov/2020 10:40'	System	09 Nov 2020 15:40:20

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:04:12

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 21:03:14
Reviewed for Safety.		16 Nov 2020 14:17:28
User entered 'I'		09 Nov 2020 15:40:20

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:12

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.		22 Oct 2020 18:43:23
User entered 'USA-US060-2020-MRNA-1273-P301000006'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:12

Serious

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.		22 Oct 2020 18:43:23
User entered 'Yes (Y)'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:12

Death

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (D) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.		22 Oct 2020 18:43:23
User entered 'No (N)'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:12

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.		22 Oct 2020 18:43:23
User entered 'No (N)'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:12

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.		22 Oct 2020 18:43:23
User entered 'No (N)'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:12

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.		22 Oct 2020 18:43:23
User entered 'No (N)'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:12

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.		22 Oct 2020 18:43:23
User entered 'No (N)'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:12

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.		22 Oct 2020 18:43:23
User entered 'Yes (Y)'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:12

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.		22 Oct 2020 18:43:23
User entered 'Veronica'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:12

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.		22 Oct 2020 18:43:23
User entered 'Fragoso'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:12

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.		22 Oct 2020 18:43:23
User entered '6550 Mapleridge Street'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:12

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.		22 Oct 2020 18:43:23
User entered 'Houston'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:12

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.		22 Oct 2020 18:43:23
User entered 'TX'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:12

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.		22 Oct 2020 18:43:23
User entered '77081'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:12

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:14:51
DataPoint Verified.		02 Nov 2020 22:06:48
User entered 'US'	System	22 Oct 2020 18:43:30

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:12

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
	(b) (4)	
User entered '5'	System	16 Nov 2020 14:17:45
User entered '4'	System	09 Nov 2020 15:40:20
User entered '3'	System	03 Nov 2020 15:39:15
User entered '2'	System	02 Nov 2020 22:15:06
User entered '1'	System	22 Oct 2020 18:43:30

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 17:04:12

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 21:03:14
User entered '16/Nov/2020 09:17'	System	16 Nov 2020 14:17:45

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 17:04:12

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 21:03:14
User entered 'I'		16 Nov 2020 14:17:45